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Improving Management of Chronic Heart Failure by Implementing a Provider In-Home Visits Program

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Degree to be awarded: Master of Public Health

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Improving Management of Chronic Heart Failure by Implementing a Provider In-Home Visits Program

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Abstract

Chronic Heart Failure (CHF) is a common medical problem affecting approximately 5.8 million people in the United States and about 26 million people worldwide. CHF is a chronic and progressive clinical condition in which the heart is not able to meet the body's needs, usually due to coronary heart disease, long-term hypertension, diabetes, or other baseline heart diseases. It is the most common cause of hospital admissions in the US.

According to the ACC/AHA, close to 25% of patients hospitalized with CHF are readmitted to the hospital within 30 days and 50% are readmitted in the first 6 months after discharge. Evidence suggest that close follow up (in the first month) after discharge from Emergency Department (ED) visit, by a physician who knows the patient have better outcome than those without follow up, or who were followed by a non-familiar physician.

About 30% of patients at the Grady CHF clinic fail to keep their appointments for different reasons. This at high risk population of patients would benefit from other options to receive outpatient medical care for CHF disease and prevent its complications. The aim of this proposal is to improve the management of CHF among patients who miss their appointments in CHF clinic and have higher rate of ED visits, admissions and readmissions to the hospital and poor quality of life (QOL). The main hypothesis is that in-home medical visits can help improve the management of CHF in this population, help decrease ED visits, hospitalizations and re-hospitalizations, and improve their quality of life. Upon completion we will learn the attitudes and acceptance of the patients toward the program and the challenges that prevent them from being compliant with the clinic visits will provide in home medical care to the patients that cannot keep their appointments. The study is innovative since there is not any specific in-home medical visit program addressing the needs of this population at Grady.

Improving Management of Chronic Heart Failure by Implementing a Provider In-Home Visits Program

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Chapter I

Introduction

Chronic Heart Failure (CHF) is a common medical problem, affecting 5.1-5.8 million people in the United States, (Roger et al., 2012), and about 26 million people worldwide (Ponikowski et al., 2014). It is a chronic and progressive clinical condition in which the heart is not able to pump or fill enough blood to meet the body's needs, usually because of heart disease such as myocardial infarction (heart attack), long-term hypertension, diabetes, or other baseline heart diseases.

The prevalence of CHF increases with age, with 8.4 % of individuals 75 years and above and 17.4% of those older than 85 being diagnosed with the disease (Bui, Horwich, & Fonarow, 2011). It is the most common cause of hospital admissions (Ambrosy et al., 2014). According to the ACC/AHA, approximately 25% of patients hospitalized with CHF are readmitted to the hospital within 30 days of discharge (Yancy et al., 2013), and 50% get readmitted to the hospital in the first 6 months after discharge (Norton, Georgiopoulou, Kalogeropoulos, & Butler, 2011)). It is a significant economic burden, with an estimated cost of US$32 billion per year (Go et al., 2013), which represents about 1-2% of the total national healthcare costs. Approximately 80% of these expenditures are in hospitalizations (Bui et al., 2011). According to the Agency for Healthcare Research and Quality's Health Care Cost and Utilization Project, appropriate outpatient management is essential to preventing frequent admissions and readmissions to the hospital. Readmissions due to CHF are now penalized by the Centers for Medicare & Medicaid services (CMS) in the form of lower reimbursements to hospitals with higher readmissions rates. Patients who miss appointments to the heart failure clinic regularly are more likely to be affected by the complications of the disease, including readmissions, lack of compliance with prescribed medications, and poor quality of life in general.

Improving Management of Chronic Heart Failure

To address the burden of frequent visits to the Emergency Department (ED), frequent hospitalizations and poor quality of life in patients with heart failure, medical institutions have implemented clinics dedicated to follow up on those patients soon after discharge from the hospital to establish regular care for better management of the disease and, therefore, reduce no shows and (by extension) readmissions. Grady Memorial Hospital in Atlanta has such a CHF Clinic staffed by cardiologists, internal medicine physicians, nurse practitioners, and other supportive staff.

Despite the very supportive and accessible Heart Failure Clinic at Grady, the no-show rate remains at 30-50% (Heart Failure Clinic report, 2017). Patients with different challenges, particularly those with psychosocial and economic barriers, continue to miss their clinic appointments frequently. Castro and Ilksoy (2015) conducted a telephone survey contacting patients 48 hours after missing their appointment at the Grady CHF clinic inquired about their medical and community barriers that prevented them from keeping the appointment. This survey revealed forgetfulness, lack of reminder or scheduling errors as the main reasons for missing appointments, followed by lack of transportation and financial issues. The population at the Grady CHF clinic faces socioeconomic challenges that put the patients at risk of missing appointments, getting clinically decompensated, having admissions and readmissions to the hospital, and decreasing their quality of life.

There is a need for an alternative way for this patient population to receive medical care that allows them to receive treatment and management for their disease. Vulnerable patients that are not able to keep their clinic appointments could benefit from providers home care visits. Studies have shown that home care can decrease the number of visits to the emergency department, hospitalizations, and costs for patients with heart failure that are homebound (Punchik et al., 2017). Because home-visit programs in combination with multidisciplinary CHF clinic interventions can reduce hospital readmissions and improve survival for patients with CHF (2014), we propose the implementation of in-home provider visits to patients that are unable to keep their appointments due to psychosocial, economic and community barriers. To accomplish the overall goal of this project, this project will address three specific aims. One aim is to identify patients who miss more than one appointment in a month at the Grady CHF Clinic by chart review. Electronic medical record (EMR) will be reviewed to identify patients at high risk for missing appointments such as those with untreated psychiatric illness/es, substance abuse, previous number of no shows, limitations to ambulate or those with more than 2 other comorbidities. This proposal hypothesizes that patients with uncontrolled mental illness, substance abuse or limitations to ambulate are at higher risk of missing their appointments and getting frequent ED visits and admissions to the hospital.

Another aim of the project is to select a sample of the identified population at high-risk for missing appointments to conduct a focus group to explore the factors affecting their ability to get to their clinic visits. The focus group will explore what the participants think about the proposed in-home visit program, how they believe it will help, and will identify potential barriers for the implementation of the program. This aim is based on the hypothesis that getting input from the patient population in study can facilitate the success of the in-home provider visits program and provide information on how to overcome the specific barriers identified to miss the appointment at the CHF clinic. The last aim is to conduct in-home provider visits with the patients selected for a six-month period and to provide them with the regular medical evaluation and plan of care equivalent to a regular visit to the CHF clinic. This is based on the hypothesis that providing the in-home provider's visit to patients that are unable to keep their appointments can prevent them from decompensation of the disease, visits to the ED, getting admitted to the hospital, and improve their HRQoL.

Theoretical Framework

The intervention in this project will be based on two behavioral theories: *The Health Belief Model (HBM),* and *The Theory of Planned Behavior*. The HBM is a theory of health behavior developed in the 1950's by social psychologists Irvin M. Rosenstock, Godfrey M. Hochbaum, S. Stephen Kegeles, and Howard Leventhal at the US Public Health Services, it applies to predict some health-related behaviors, including behaviors related to chronic diseases (Janz & Becker, 1984). The model suggests that "people's beliefs about health problems, perceived benefits of action and barriers to action, and self-efficacy explain engagement or lack of engagement in health-promoting behavior." In addition, a stimulus must also be present to trigger the health-promoting behavior. In other words, the individual should perceive a benefit of the health promotion that outweighs the cost of the recommended behavior. Once the person feels susceptible to certain level of threat, under certain psychosocial factors and certain level of information and education, they will be more likely to adopt the action. Furthermore, the health promotion interventions should emphasize the benefits of the suggested health behavior, while including measures to minimize the barriers. For example, patients with CHF should perceive themselves as susceptible to the decompensation of the disease and severity of the disabling symptoms such as shortness of breath and its effect on quality of life, and then they should perceive the benefit of adherence to clinic appointments and medical treatment to prevent the harm of the exacerbation/hospitalization with the fewest barriers possible.

In addition, *The Theory of Planned Behavior* will be applied. According to this theory, if a behavior is perceived to be important, the individual/family will be more likely to engage in that behavior if they also perceive that it is within their control (Ajzen, 2011). By experiencing better control of the disease, a sense of worthiness of adherence to therapy, along with education, and the perception of control on the actions to manage their CHF, the intention of adopting the behavior will be triggered. Based on quaternary assessment of QOL, once initial adherence to medical recommendations through the in-home visits is accomplished, patients will be offered the option of being reincorporated in the CHF clinic.

Significance of the Study

This will be the first intervention at Grady Memorial Hospital that involves regular provider in-home visits to patients with CHF and provides medical care to patients who fail to complete outpatient follow-up due to medical or community barriers. As the population ages, the prevalence of CHF is projected to increase, with about 10% incidence per year after age 65 (Roger et al., 2012) As one of the CMS metrics demonstrates, readmissions because of poor outpatient management represent a burden to the health care system. The overarching long-term goal is to design and implement a patient centered intervention that will improve the management of CHF and decrease hospitalizations among patients who miss their appointments to the Grady CHF clinic by providing in-home visits and facilitating ways to overcome the identified barriers which lead to missed appointments. Outpatient care through this pilot in-home visit program will improve patient's quality of life (QOL); will help decrease visits to the ED, and reduce admissions to the hospital. This preliminary work could lead to larger scale interventions in this population and potentially address a broader array of co-morbidities during each in-home visit.

Chapter II

Literature Review

Chronic Heart Failure (CHF) is a chronic disease that affects 5.8 million people in the United States (ACC/AHA 2013) and over 26 million worldwide. It is the most common cause of hospitalization in patients over 65, being the cause of over one million hospital admissions every year in developed countries (Ambrosy et al., 2014). In-hospital worsening of CHF is associated with mortality, thus the goal is to avoid admissions that can be prevented (DeVore et al., 2014). Outpatient management is essential to prevent decompensated CHF and prevent hospital admissions. Although clinics are available, many patients are not able to keep appointments and consequently suffer decompensation that requires inpatient care. Grady Memorial Hospital (GMH), an academic center in Atlanta, Georgia has a CHF clinic with high no-show rates. An in-home care program can provide health care access for patients who are unable to attend outpatient appointments that can prevent decompensation, hospital admission and readmission, and improve quality of life. This chapter summarizes the burden of CHF to patients and their families, the importance of outpatient care for proper disease management, and issues with hospitalizations and re-hospitalizations, the CHF clinic at GMH, and benefits of in-home care for patients with CHF.

Overview of Patient and Family Burden Associated with CHF

Chronic heart failure represents a big burden to individuals, their families, and the health care system. It is a serious public health problem, being the most common cause of hospitalization in patients over 65, and the cause of over one million hospital admissions every year in developed countries (Ambrosy et al., 2014). Despite advances in treatment, the mortality of the disease remains high, approximately 50% at 5-years after diagnosis (Goldstein, May, & Meier, 2011). This problem underscores the importance of developing and implementing initiatives to improve the management of the disease.

Physical and Psychological Effects of CHF

Shortness of breath, fatigue, lower extremity swelling, and other symptoms of decompensated CHF can cause significant limitation to the patient's capability to perform their activities of daily living. It means that the patients and their families experience the burden of the physical symptoms and the negative emotional effects of the disease due to a poor quality of life. Studies have shown that CHF affects not only the patient, but also their families who also face the burden of this progressively disabling disease. Ponikowski et al (2014) found that CHF significantly affects the patients and their families' quality of life causing anxiety and depression. Furthermore, a study performed by Jeon et al (2010) showed that it is also a cause of isolation and sense of lack of control. These findings stress the importance of approaching disease management from a multidisciplinary approach that incorporates patient's families and addressing not only the physical issues in CHF, but the psychosocial aspects as well.

Current Care Methods Used for Diagnosis and Care of CHF

The current methods for taking care of patients with CHF constitute a series of interventions that start with the diagnosis of the disease followed by a sequence of measures to follow up the patients over the course of the disease.

The treatment of CHF points towards initiating evidence-based pharmacological treatment as well as non-pharmacological interventions. The pharmacological management involves several evidence-based drugs indicated based on the stage of disease (ACC/AHA, 2013). The non-pharmacological measures are included at all the steps on the ladder and involve education and lifestyle recommendations (ACA/AHA, 2013), like restricted salt and fluid intake, adherence to medication and clinic appointments, and other aspects relevant to keeping the disease under control.

Structure of Care of CHF

When patients present to a primary care clinic or ED with clinical symptoms and signs of CHF, the provider initiates diagnostic testing and evidence-based medical therapy according to the presentation. At the initial encounter the provider starts the process to coordinate the following steps for structured follow up recommended for these patients based on the American Heart Association and the American College of Cardiology guidelines (ACC/AHA Guidelines, 2013). This section illustrates the current management of CHF from diagnosis, initial visit, follow up, and other components of the multidisciplinary care of patients with chronic heart failure.

Diagnosis and initial visit for CHF.

The diagnosis of CHF is based on history and physical data collected at the initial presentation to the primary care office or ED with symptoms of shortness of breath, fatigue, and signs of volume overload. At that moment, management begins by treating the patient with the recommended drugs, followed by diagnostic testing, like plain films of the chest, electrocardiograms, and cardiac ultrasounds that confirm the type of CHF diagnosis. Once the diagnosis of CHF is established, further testing is performed to assess for possible reversible causes (Hunt et al., 2009).

Follow-up visits and their importance for maintaining health for those with CHF.

Continuity is vital to maintaining health outcomes and quality of life for patients with CHF. Getting evidence-based therapy and the necessary adjustments by a regular provider can help improve survival and decrease hospitalizations and readmissions in patients with heart failure (Gheorghiade, Vaduganathan, Fonarow, & Bonow, 2013). The diagnosis of CHF in the clinic or the hospital is accompanied by initiating a medication regimen and education, followed by a referral to a specialized CHF clinic for outpatient follow up. The team sees the patient on regular basis and follows up on prescribing and adjusting the medication regimen, education on the self-management of lifestyle measures recommended, and maintaining the disease in a compensated state.

Apart from regular follow up in a CHF clinic, reinforcement to ensure adherence to recommended guidelines is important in the management of CHF. This was demonstrated by the IMPROVE HF study (Registry to Improve the Use of Evidence-Based Heart Failure Therapies in the Outpatient Setting), a large performance improvement (PI) intervention that tested the use of guidelines by 167 outpatient cardiology practices on almost 35,000 patients that assesses seven quality measures on the management of CHF, including medications, implantable cardioverter defibrillator, CHF education, and others. The intervention demonstrated significant improvement in the use of evidence-based therapy according to guidelines in patients with CHF in the outpatient setting (Fonarow et al., 2010). Although this PI was performed in outpatient cardiology clinics only, the worthiness of the specialized care has been reproducible in CHF clinics staffed by providers with expertise in CHF. It means that the findings of the IMPROVE-HF PI call attention to every provider taking care of this population to make sure patients are on the recommended regimen for optimizing medical treatment in patients with the disease. Given the complexity of the patients with CHF, a multidisciplinary team approach has been recommended for this population.

Team and Evidence-Based Approaches

Since CHF is more common in the older population, it is usually associated with multiple physical and psychological co-morbidities that require simultaneous interventions by different disciplines. Several initiatives have concluded that a team approach is the most helpful for patients with CHF (McAlister, Stewart, Ferrua, & McMurray, 2004), given that it is associated with high quality care, in addition to being cost effective for the healthcare system (Reilly et al., 2015). According to Olsen, Saunders, et al, 2011, "the goal of the interdisciplinary team is to provide care that is safe, cost effective and cultural and linguistically appropriate interventions in every care setting". CHF patients because of their complexity and common association with multiple co-morbidities can do better with such approach. The team care for patients with CHF is implemented through disease management programs (DMP), recommended by the American Heart Association (AHA). These programs contain structured treatment plans implemented by a multidisciplinary team for people with chronic diseases like CHF.

The multidisciplinary approach to taking care of patients with CHF includes outpatient care by an interdisciplinary team of a primary care provider, cardiologist, nurse, pharmacist and other staff for social support. This team ensures that patients receive an individualized care for the disease, that they are on the evidence based medical regimen and receive comprehensive education for the proper self- care to reduce complications and hospitalizations (Gheorghiade et al., 2013). At the same time, the DMP model of care aims with a good flow of communication with providers and assessment and progress of patients. This indicates that the complexity of CHF patients makes them an ideal target population for this model of care. The national CHF guidelines recommend a team model of care that includes key elements of a CHF DMP model, such as point CHF clinics, home care and telemonitoring, to facilitate adherence to practice evidence-based interventions.

Evidence-based medications.

The guidelines for management of CHF are updated yearly, and reinforce on the use of medications that have shown to improved mortality and/or morbidity, such as angiotensin converting enzyme inhibitor (Packer et al., 1996), angiotensin II receptor blockers (ARB) (Carson, Tognoni, & Cohn, 2003), beta blockers (Fowler et al., 2001), and others. This is complemented by improved QoL and less hospitalizations with education on self-management of the disease (Dunbar et al., 2015) (Reilly et al., 2015). A randomized clinical trial performed by Dunbar (although it included patients with CHF and diabetes) showed improved perceived general and HF related QoL, but no diabetes. Reilly's economic evaluation of a self -care intervention in patients with CHF and diabetes demonstrated lower cost without negatively impacting quality-adjusted life-years. Medication adherence is another component of self- care, since medication use must be reviewed and adjusted periodically according to patient response, efficacy and tolerance and/or side effects. Compliance with the use of evidence-based recommended regimens is vital to help keep the patients out of the hospital and improving quality of life.

Education and Counseling

Several of the interventions in the management of CHF are to be carried out by the patients and their families, which makes education an essential element to be delivered by the team of providers in an individualized and systematic patient-family centered approach.

Specialized CHF Clinics

The Heart Failure Society of America made a consensus statement in 2008 which reinforces that the CHF clinics run by team members in different disciplines with the in-common expertise in the management of CHF, are a crucial element to delivers structured specialized medical care that focuses on the disease with a patient and family centered approach. This has been important for medical institutions to implement, reinforce and support the CHF clinics (Hauptman et al., 2008).

The concept of specialized CHF clinics has been introduced more than three decades, by Cintron, 1983. He found out that this modality of care can decrease mortality, and hospitalizations, while increasing quality of life at a lower cost. The model has been further developed when several studies have consistently demonstrated the benefits of the CFH clinic team approach model when compared with a regular clinic (Howlett, 2014). Grady Memorial Hospital has had a CHF clinic since 2011.

Grady Memorial Hospital CHF clinic.

Grady Memorial Hospital is a 1000 bed public academic safety net hospital that delivers medical care to the underserved population of Atlanta, Georgia. In response to the high volume of yearly admissions for CHF, GMH implemented a CHF team in 2011 that provides consultation to patients hospitalized due to decompensated CHF and follows them to transition to outpatient CHF clinic within 1-2 weeks of discharge. The clinic has seven healthcare providers and operates Monday through Friday. Patients in the program receive follow up phone calls within 72 hours of discharge, including reminders for their appointments as well as the option to walk into the clinic. According to the Grady Heart Failure Quality Metrics report, in 2016 there were 566 admissions for decompensated CHF, and 87% of the patients received the follow up phone call. Only 37% adhered to a follow up visit within 7 days of discharge or less. Of those patients, 25 % were readmitted within 30 days. This percentage is slightly above the reported 23% readmission rate for decompensated CHF from 2009 to 2012 nationwide (Go AS, et al, 2015). The CHF clinic at Grady offers substantial services to the patients; however, the no-show rate is 30%, of which, these individuals have a higher frequency of admission and readmission to the hospital. An intervention that provides evidence-based medical care to those patients can improve their quality of life and decrease visits to the ED and hospitalizations. A systematic review showed that home care can improve the outcomes in patients with chronic disease who cannot go to their clinics, and improve their functional status (Markle-Reid, Browne, & Gafni, 2013). This finding reiterates previous results of a small study performed by Aguado, 2010, which showed that provider home visits for education can help decrease hospital readmissions, visits to the ED, and healthcare costs in general. Importantly, this suggests that "bringing the clinic" to high risk patients through a home visit program can significantly help on better outcome in patients with limitations to attend clinic appointments.

An important role of the CHF clinic is to educate patients on how to identify their need to go to the hospital early when suspecting decompensation. For example, congestion represents the initial mechanism of decompensation of CHF, and it can take days to weeks before the individual becomes symptomatic (Gheorghiade et al., 2013). Thus, it is important to recognize early signs of congestion to prevent decompensation of the disease. Studies have shown that self-care measures such as the lack of early recognition of congestion by the patients, poor knowledge, and non-compliance with treatment are important triggering factors for CHF decompensation (Arcand et al., 2011).

If the CHF symptoms are not treated early enough, decompensated disease can result on admission and readmissions to the hospital, and its subsequent complications. Adherence to appointments in the CHF clinic is crucial for the adjustment of medical regimen and other non-pharmacological measures. The CHF clinic at Grady has a 30-50% no show rate, and patients who miss several appointments are at risk for decompensation of the disease.

Missing appointments: causes and consequences.

Patients that are not able to keep their appointments are at higher risk to get frequently decompensated due to lack of adherence. Studies have found that several factors such as age, sex, and language concordance have been associated with missing appointments. A large retrospective study performed in an urban, academic, underserved outpatient internal medicine clinic from January 2008 to June 2011, demonstrated a 45% rate of "no-show". Furthermore, the strongest risk factors identified were the number of previously missed appointments and the wait time (Ziaeian & Fonarow, 2016).

Although several studies have been performed on causes for high no-show rates, few, if any, studies have been on the challenges or factors specifically associated with missing appointments with CHF patients. A telephone survey conducted on patients who had "no show" appointments at the Grady CHF clinic in 2015, revealed forgetfulness, lack of reminder or scheduling errors as the main reasons to miss appointments, followed by transportation and financial issues. These results were based on the 40% of 145 patients attempted to reach, since 60% were not reachable by phone after 3 attempts. This shows a lack of stability on how to locate patients for appointments arrangements. Some studies have been conducted in clinic of other specialties, such as one in an otolaryngology clinic in Detroit that showed race and income as significantly related factors to missing clinic appointments (Miller, Chae, Peterson, & Ko, 2015). Although this happened in different clinic setting, the socio-economic factors studied can be validated to populations with similar financial challenges like the population at Grady Hospital.

The lack of medical follow up due to missing clinic appointments has a negative impact on the management of chronic diseases like CHF. It decreases continuity and quality of life in addition to contributing to poor medications adherence and the subsequent decompensation of the disease, such as hospitalizations and re-hospitalizations.

Issues of Hospitalization and Re-hospitalization

Suboptimal outpatient management of CHF can cause the decompensation of the disease that frequently results on admissions and readmissions to the hospital and its negatives consequences.

Hospitalization and re-hospitalization rates.

CHF is the fourth cause of hospitalization and the main cause of hospitalization for cardiac disease in the US (Pfuntner, Wier, & Stocks, 2006). It adds significant expenditure to the healthcare system, and about 80% of the 21 million dollars expended in CHF related care in 2012 was in inpatient care (Heidenreich et al., 2013). It means that strategies to reduce CHF related hospitalizations are important to reducing health care expenses.

According to the ACCH/AHA, nearly 25% of patients hospitalized with CHF are readmitted to the hospital within 30 days (Yancy et al., 2013), and 50% are readmitted within the first 6 months after discharge (Norton et al., 2011). Furthermore, one meta-analysis demonstrated that only about 25% of hospital readmissions within 30 days post-discharge can be prevented (van Walraven, Jennings, & Forster, 2012). This supports that since readmissions represent a burden for the patient, family and the health care system it is worthy to target the preventable ones.

A review performed by Ziaeian, Fonarow, 2016 on the interventions that have shown to reduce readmissions and improve hospital performance on the 30-day, stated that despite the broad evidence -based therapies for management of CHF, it is vital to continue to develop initiatives and new strategies to prevent readmissions.

Factors associated with increased re-hospitalization

Studies looking at the reasons for readmission for CHF have shown that worsening of disease is the main cause for re-hospitalization (Butler et al., 2008). Several physiological, socioeconomic and psychological patient and system related factors are associated with the worsening of CHF and the consequently increased admissions and readmissions (Anderson et al., 2006). This means that the natural history of the disease is influenced by these factors, which can impact patient outcome. A broader research exploring on the reasons for readmission for CHF from different perspectives, revealed that 36% of caregivers, 56% of patients, and near 65% of health care providers considered comorbidities, nonadherence and suboptimal medication as contributing factors to readmissions (Annema, Luttik, & Jaarsma, 2009). This supports that the reason for readmissions for heart failure is multifactorial, and involves providers, patients, families and their environment, as well as system related factors. This calls for the attention for interventions that address the problem looking at the broad spectrum of potential causes. It is imperative to address the problem with programs such as the in-home provider visits proposed to deliver care to patients at risk of not being able to keep up with their appointments.

A matched pair case-control study in Canada on the factors associated with 7- day readmissions after discharge for CHF, showed that early readmission is associated with age 75 and older, 3 or more comorbid conditions and requiring assistance with activities of daily living (Eastwood, Quan, Howlett, & King-Shier, 2017). Although this was a small study, focused on patients with signs of frailty only, giving that CHF is more common in the elderly, the findings support the proactive approach of addressing this target population.

Incentives for preventing re-hospitalization

CHF not only has a high prevalence and incidence, with 5.8 million (about 3%) of people suffering the diagnosis, and 10 per 1000 new cases each year after age 65 (Roger, Go, Lloyd-Jones et al), but it is also a main cause of admission to the hospital. Admissions due to decompensated CHF represent 1-3% of all hospital admissions in U.S. and European countries (Neumann et al., 2009). In the past 3 decades, the number of admissions for CHF per year has increased from

800,000 to over a million as a primary diagnosis, and more than 2 million as a primary or secondary diagnosis with a 50% increase trend (Lloyd-Jones et al., 2010).

Despite the progress on evidence-based therapy for CHF, the disease continues to be a common cause of readmission to the hospital, with near 50% rate of readmission within 6 months of discharge and, according to Medicare, more than 20% readmission within 30 days after discharge (Medicare Payment Advisory Commission, 2008).

In 2013, the Centers for Medicare and Medicaid Services started to penalize hospitals with readmission rates higher than the expected risk-adjusted readmission rates for CHF (Patient Protection and Affordable Care Act, 2010). This has made hospitals focus on initiatives with interventions that target to prevent readmissions for CHF. This initiative involves the patient's families as an important element to help in their care and prevent hospitalizations.

Role of the Patient's Family and Environment when Taking Care of CHF

The home has been demonstrated to be an essential environment for the process of education and ambulatory care of patients. It has been a target of randomized clinical trial on patients recently discharged after admission for CHF decompensation. The study explored the effect of home education on self-care knowledge on the management of CHF, and after 6 months, it showed that knowledge was improved, and adherence to treatment was significantly higher in the intervention group with a p value <0.001 (Mussi et al., 2013). In addition, care of CHF patients involves several lifestyle related actions that can be optimized by the involvement of the patient and their family, and by getting to know their home environment.

To get the family involved in the treatment of patients with CHF the provider recommends home visits intervention, such as the one presented in this thesis, which allows the opportunity for interacting with several family members as well as being in the patient's environment, that can build up the foundation for the overall self-management of the disease. The benefit of this intervention can be supported by Riegel (2013), who defined self-care in heart failure as "positive behaviors leading to decisions and actions that an individual can take to help maintain clinical stability and cope with the disease". Furthermore, according to another randomized controlled clinical trial designed to assess the effectiveness of an educational program in nursing, educational meetings and home visits, the educational interventions were beneficial on the self- care of patients with CHF (Rodriguez-Gazquez Mde, Arredondo-Holguin, & Herrera-Cortes, 2012). This concept is applicable to patients who cannot follow up in clinic for different reasons, such as the study population in this program.

Getting the families of patients with CHF involved in their care is important in the management of the disease, and this can be facilitated by in-home visits. For instance, one retrospective study found that home care for homebound patients with CHF reduces healthcare service utilization and overall cost (Punchik et al., 2017). In addition, this retrospective study showed that home care for homebound patients with HF reduces healthcare service utilization and overall cost. The home visit project presented in this proposal will benefit patient at the CHF clinic at Grady that are unable to adhere to their clinic follow up.

Provider in-Home Visits in Patients with Chronic Diseases and CHF

In-home provider visits can improve outcome in patients with CHF. The comparison of a 6 months pre-visit versus a home visit period showed a decrease in hospitalization and ED visit by 47% and 46%, respectively. In addition, it demonstrated a 67% decrease in length of stay for CHF and 24% overall costs reduction (Punchik et al., 2017), it means a significant impact from the individual and public health standpoint.

To help patients with chronic diseases maintain a high quality of life, prevent visits to the ED, and reduce hospitalizations, researchers have studied several interventions in the outpatient setting, such as structured outpatient clinic with cardiologist, nurses, and telephone follow up by clinician within 72 hours of hospital discharge and regular visits. Among those interventions, In-home visits have been found to help provide medical care to patients who are unable to keep up with their visits to the clinic (Punchik et al., 2017). Another aspect related to this improvement in outcomes may be related to familiarity with the attending physician. An in-home visit program by a provider who the patient is familiar with can be beneficial for patients with heart failure. This importance of familiarity with the physician was supported by a large retrospective cohort study in Canada. In this study, patients with heart failure who had been treated in the ED, and who had a follow up within a month of being treated by a physician who knew the patient had better outcome than those without follow up or who had a follow up with a non-familiar physician (Sidhu, Youngson, & McAlister, 2014). This study could have an external validity limitation, given that most of the centers will have staff and time constraints that could prevent for the visit to be performed by the same provider.

In addition to in-home visit programs providing patients with familiar providers and, therefore, better outcomes, studies have also demonstrated substantial cost-effectiveness of such programs. For example, the WHICH study, a multicenter randomized clinical trial showed that there is no significant difference between home-based interventions and clinic care, but significantly lower costs associated with healthcare provided at home (Stewart et al., 2012). The extended follow up portion of the study showed that taking care of the patients at home may be cost effective in elderly population with heart failure (Maru et al., 2015). A systematic review and cost analysis comparing provider home visits to hospital and clinic-based care for patients with heart failure showed that home visits were beneficial due to increased survival rates, decreased hospitalizations, and increased cost effectiveness (Fergenbaum, Bermingham, Krahn, Alter, & Demers, 2015). These findings were confirmed by Laborde-Casterol et al (2016), who conducted a large multicenter prospective observational study in France that showed that a multidisciplinary community program that involves providers home visits may improve the one-year mortality related to the disease.

Patients in-home visit programs need continuity of care and regular visits. Echeverry, 2015, found that monthly and as needed provider home visits to patients with advanced heart failure that are homebound, significantly improved hospitalization rates, visits to the ED, and 30-days readmission rates (Echeverry, Lamb, & Miller, 2015), this was a small study. According to a across-sectional qualitative study on the top factors taking into consideration for the frequency of in-home visits include some patient related factors, such as the clinical condition and compliance to medications or presence of a caregiver, provider related aspects like workload, professional experience, as well as compliance to medications (Achil, Zanini, Gattesco, & Palese, 2013).

The lack of medical follow up for patients who miss appointments at the CHF clinic results in decompensation of the disease, increased number of visits to the ED, hospitalizations, and healthcare costs, and decreased quality of life.

This study is significant because it will be the first intervention at Grady Memorial Hospital that involves regular provider in-home visits to patients with CHF and provides medical care to patients who fail to complete outpatient follow-up due to medical or community barriers. The overarching long-term goal is to design and implement a patient centered intervention that will improve the management of CHF and decrease hospitalizations among patients who miss appointments at the Grady CHF clinic by providing in-home visits and facilitating to overcome the barriers identified to miss their appointments. This pilot project will serve as the foundation for other similar programs to improve the management of this serious condition. Outpatient care through the home visit program will improve patients QOL and will decrease visits to the ED and admissions to the hospital in this vulnerable population.

Chapter III

Methodology

This thesis is a grant proposal in response to the National Institute of Health (NIH) announcement for an R-01 for "Improving Heart Failure Disease management" (PA-07-355) PA-07-355: Improving Heart Failure Disease Management (R01). It is a request for funding to implement an in-home provider visit program for patients who are not able to keep their appointments at the Heart Failure clinic at Grady Memorial Hospital in Atlanta, Georgia.

To fill the gap on the medical care for patients who can't keep their appointments, this study will develop an in-home provider visits pilot program for the ambulatory management of patients with CHF patients who are at high risk of missing two or more appointments at the Grady CHF clinic. **The overall goal of the project is to improve the management of heart failure and decrease ED visits, admissions and readmissions to the hospital, in addition to improving quality of life among this population by implementing a provider in-home visits program.** This program will reach this goal by accomplishing three aims. The first aim is to identify patients who miss more than one appointment in a month at the Grady CHF Clinic by chart review. Electronic medical record (EMR) will be reviewed to identify patients at high risk for missing appointments such as those with untreated psychiatric illness/es, substance abuse, previous number of no shows, limitations to ambulate or those with more than 2 other comorbidities. This proposal hypothesizes that patients with uncontrolled mental illness, substance abuse or limitations to ambulate are at higher risk to miss their appointments and get frequent ED visits and admissions to the hospital.

The second aim is to select a sample of the identified population at a high-risk to miss appointments for conducting a focus group to explore the factors affecting their ability to get to their clinic visits. The focus group will explore what the participants think about the proposed in-home visit program, how they believe it will help, and will identify potential barriers for the implementation of the program. This aim is based on the hypothesis that getting input from the patient population in study can facilitate the success of the in-home provider visits program and provide information on how to overcome the specific barriers identified to miss the appointment at the CHF clinic. The last aim is to perform in-home provider visits to the patients selected for a six-month period and provide them with the regular medical evaluation and plan of care equivalent to a regular visit to the CHF clinic. This is based on the hypothesis that providing the in-home provider's visit to patients that are unable to keep their appointments, can prevent them from decompensation of the disease, visits to the ED, getting admitted to the hospital, and improve their HRQoL.

The inclusion criteria are: having a diagnosis of CHF, being a patient at the Grady CHF clinic age 45-year-old or older, and having 2 or more consecutive no shows in clinic in the past 6 months. In addition to the criteria listed above, those with psychiatric illnesses or substance abuse and two or more comorbidities will be included in this high-risk group. Exclusion criteria are: being younger than 45 years old or having a diagnosis of cancer.

First, patients who miss two or more consecutive appointments in the past 6 months at the Grady CHF Clinic by chart review will be identified. Patients at high risk for missing appointments and its negative consequences of frequent ED visits, admissions and readmissions, and decreased QoL, will be determined through review of electronic medical records (EMR).

Second, a sample of those identified as being at high risk will be invited to attend a focus group related to the factors affecting their ability to get to the clinic visit, to explore how they think that the in-home provider visit program will help and what are the potential barriers for the implementation of the program. Finally, based on feedback from the focus group, in-home provider visits will be performed at the patient’s homes over a six-month period.

The in-home provider visits will provide the patients with regular medical evaluation and a plan of care equivalent to a regular visit at the Grady CHF clinic had they been able to attend their appointment there. This program will utilize one of the offices at the CHF clinic which has been discussed and arranged with the clinic management, who will act as program manager. The office has two desks and office supplies will be available. A laptop with internet access will be used for the data collection and documentation of the visit findings. **The team** will consist of one cardiologist, one internist, 2 nurse practitioners with expertise in the CHF management, a pharmacist, and one nurse. The staff will be reassigned from the heart failure clinic through rearrangement to prevent the need to hire new personal. The visits will be performed by the one of the providers, who will be qualified to make changes and recommendations such as medication dosage adjustment and or order new prescription/s to the pharmacy. The provider will be able to draw blood to check stat potassium, magnesium, and creatinine and make medications adjustments based on results. For the home visit, the provider will need a sphygmomanometer, a stethoscope, and a pulse oximeter. A scale will be provided to each patient on the first visit to keep record of the patient's weight. The provider will assess and determine if patients are found to be decompensated during the visit and will decide on the need for hospitalization. On the first visit, an initial assessment will be performed based on the New York Heart Association (NYHA) and the Minnesota Living Heart Failure Questionnaire (MLHFQ), an instrument that measures the effect and treatments for CHF on the person's ability to live as they want. This instrument was originally used by Rector et al, 1992, for the assessment of patient outcome during a randomized, double -blind, placebo-controlled trial. The tools will be used to evaluate the patient's clinical and functional status of the intervention and control groups of the study at the beginning and 12 months later to evaluate change on ED visits, admissions and readmissions and quality of life between the two groups. The results will be statistically analyzed with the assistance of a statistician.

The project is supported by the Chief of Cardiology and counts with the chief of the Heart failure clinic at Grady as a collaborator. The Performance Improvement Department is also supportive of this project as well. See letters of support in Appendix 4.

Review of the Types of funding agencies

Congestive Heart failure is a significant cause of morbidity and mortality and several evidence-based interventions have shown to improve outcomes. In an attempt to promote the stability of the disease, several funding agencies provide support to researchers to work on projects with target to improving the conditions of patients with heart failure. A review of the Web of science database on "improving heart failure disease management" revealed 278 funding agencies for this purpose, with the top ones being the National Heart, Lung and Blood Institute, The National Institute of Health, Novartis and Medtronic.

Summary of the Grant Announcement

After reviewing the Web of Science Database, based on the number of granted awards for projects on congestive heart failure, I chose to respond to the program announcement (PA) number PA-070355 of the National Heart, Lung, and Blood Institute (NHLBI), the National Institute of Nursing Research (NINR), and National Institute on Aging (NIA), which is a R01 for Improving Heart failure disease management.

The announcement was released on April 13, 2017, the opening date: May 5, 2017, and a letter of intent is not needed.

This initiative has the purpose to stimulate researchers to study areas that have room for improvement and better implementation of interventions for better management of chronic HF. The size and duration or the award may vary depending on the project, and institutions of Higher Education are eligible to apply. In addition, the principal investigator should have the skills, knowledge and resources to conduct the project. As an internal medicine faculty physician and an

MPH student at Emory University, taking care of several patients with CHF in the outpatient and inpatient settings, I can fulfill the requirement as investigator for the proposal. In addition, Dr. Modele Ogunniyi, Associate Professor of Cardiology at Emory University, Co-Director of the Heart Failure Clinic at Grady Memorial Hospital will provide the support as field advisor for the concretization of this project.

Grant Review Process

The grant proposal has been submitted to my Thesis Chair, Dr. Grant Baldwin, Dr. Ogunniyi, Cardiologist, field advisor, and 3 more reviewers via email for their review and critique by using track changes and comments. The NIH review criteria based on guidelines have been also sent to them for reference to evaluate the proposal for: significance, investigator expertise, innovation, approach and environment (See Appendix 1).

The received written suggestions and constructive comments will be incorporated into the document. The proposal will then be resent to them for a second review.

Grant Proposal Reviewers and their Expertise

The thesis has five reviewers: Drs. Anekwe Onwuanyi, MD; Heart Failure Specialist Cardiologist; Antoine Trammell, MD, MPH; Saumeth Cardona, MD, MPH; and Ike Okosun, PhD. Dr. Onwuanyi is the Chief of Cardiology for Morehouse School of Medicine, he is recognized nationally as a best practice leader and director of the Heart Failure Clinic at Grady Hospital. Dr. Trammell is an Assistant Professor of General Medicine, Emory University at Grady Hospital. He has experience on the management of patients with CHF in the outpatient and inpatient settings. Dr. Cardona works in the Department of Endocrinology and has experience on research on chronic diseases. Dr. Okosun is an Associate Professor and Director of the Division of Epidemiology and Biostatistics at Georgia State University. He has extensive background in research methods, epidemiological methods, and Biostatistics, and has published over 60 manuscripts in different areas.

He is currently the Chair of the epidemiology section of the Obesity Society. The final review is being performed by my Thesis Chair, Dr. Grant Baldwin, PhD, Affiliated Professor in the Department of Behavioral Sciences and Health at Rollins Scholl of Public Health.

Optimal Protection of Human Subjects

An Institutional Review Board (IRB) exemption letter was obtained, and the project was considered not to be research. This letter was subsequently presented to the Performance Improvement Department at Grady Memorial Hospital for their approval.

Chapter IV

Critiques of the reviewers and description of incorporation of their comments

This chapter includes a list of all the critiques of the 4 reviewers, and a description of how the grant proposal was modified to incorporate the reviewer's comments.

Reviewer # 1

The reviewer suggested **clarification of semantic issues such as refer to chronic heart failure instead of congestive heart failure-** The changes were incorporated in the project summary on page 42. Reviewer also suggested including patients that had missed 2 or more consecutive appointments in the past 6 months to better identify the study time. This change was applied to Aim 1 through the entire document. In addition, he suggested including **poverty level and home distance from clinic as risk factors to miss appointments in Aim 2**, this change was also addressed and changed accordingly.

In the narrative section the reviewer recommended to **clarify that readmissions cannot be totally prevented by improving outpatient care, but only partially, since some readmissions are due to disease progression,** and the critique was included in that section on page 43.

In the Facilities and Resources section, the reviewer states that **the in-home visit provider should have the credentials and authority to make changes on medications such as adjusting dosages and/or adding needed medications, as well able to draw blood for testing.** Since medications adjustment is a factor that will impact the outcome of compensated CHF, the changes were adapted to the section on page 44.

In the specific **AIMS,** in addition to the critique mentioned on aim 1 about the patient selection time period, for Aim 2 **it was suggested to state that the sample will be randomly selected, and on Aim 3 the reviewer raised the question of what will happen when patients don't have a home?** In response, the changes were adopted, and it has been specified that the lack of an address is an exclusion criterion for patients to be part of the study. These changes can be found on page 45.

As far as the impact section, the reviewer suggested to **check on other instruments available to assess for QOL in patients with CHF,** however, the NYHA classification and the MLHFQ will still be used to measure the outcome, given that the NYHA is extensively used by clinicians to assess function in the CHF population, and studies have shown that the MLHFQ has good metric properties, and is also an extensively used instrument to assess QOL in these patients.

In the Research strategy section, as the director of the CHF clinic, the reviewer suggested that resources area **should mention that the project will use staff that is already in the heart failure clinic and will get reassigned to work on the field to see the patients in the study, so the program will not involve extra expenses on hiring new people, though will not increase cost.** This critique was adopted and included in the document on pages 46 and 53.

He also remarked that as stated in the aim section, **the providers to perform the visits should be authorized to do immediate labs to check potassium, magnesium and creatinine, and would be able to prescribe and make the needed changes according to the visit.** This has all been incorporated in to that section on page 3.

The reviewer critiqued that **it is not clear how the intervention contribution to the stability of CHF will be measured.** It was added that the NYHA and the MLHFQ will be used for this purpose. In addition, the variables such as unplanned office visits, ED visits, and readmissions will be used to measure the outcomes.

In the innovation section (B2), the reviewer recommended **to reflect that the intervention is scalable and can be applied to other chronic diseases in the future. This was incorporated in to the** section on page 48.

It was also suggested to **Include patients that are older than 70-year-old, given that they are more likely to have some community barriers to go to clinic and more co-morbidities, and to have a control group to compare results with the intervention group**. Both changes were made on page 52 and were addressed by incorporating the population 70 and older in the study.

On behalf the focus group proposed in Aim 2, it was recommended to **change sample selection from 6-8 first patients to a randomized method that will include a representation of patients with different demographic characteristics.** This was incorporated in the document on page 53.

Reviewer # 2

Reviewer 2 stated that the project addresses an important public health problem, since despite advances in management and therapeutics of CHF, morbidity and mortality does not reflect this change. In addition, the reviewer made several recommendations on grammar corrections, including that **the usual font for NIH applications in Arial 11. Margins are usually 0.5 inches".** The font was adjusted in the entire document and margins were all incorporated in to the entire document.

In the Facilities and other resources, he commented that **the proposal needs to clearly identify the team members. "The protocol for home-visits needs to be clearly documented including how patients who are deteriorating will be handled.** This was addressed in the Facilities and other resources section, page 44, stating that the team will consist of one CHF specialist cardiologist, and other team members.

Other comments included: to **list collaborators and clarify how online would be achieved.** This information was also incorporated in to the document clarifying that the providers will have internet access to use laptop for documentation.

About the innovation section, he added that the proposal applies health and research concepts including community-based participatory research to the environments in which health challenges develop, such as home and communities.

In the approach section, the reviewer recommended using **a logic/BDI model based on the social ecology**, and although this is also an appropriate framework, the HBM and the theory of planned behavior can also be helpful in this study and will be used for the study.

On the environment section, he suggested to **obtain letters demonstrating institutional support and from collaborators to strengthen the application**. Letters of support of the Grady Performance Improvement Department and of the Director of the CHF clinic have been added to the appendix.

Reviewer # 3

Reviewer 3 made several **grammar critiques**, the proposal was reviewed and I made the changes accordingly. In the project narrative, she recommended **to include the cost CHF to the Healthcare system and clarify what the CMS penalty is for hospitals in case of readmissions.** This information was added as stated in the reviewer 1 section. In addition, it was noticed that some references were missing, and they were added.

In the research plan, there is a critique on some **lack of consistency on the statement of the inclusion criteria to the project.** This was changed through the entire document.

In addition, the reviewer recommended that to **address any potential problem on reaching the patients by phone, they can be contacted via certified mail**. This has been addressed on page 52. One more concern in that section is **how the challenge of time constrains for providers will be addressed**, and this has been stated as well. One more critique included **to specify where the focus groups stated in aim 3 would take place, what would happen if the patients have motility difficulty, and what transportation would be arranged.**

Some questions were raised on **how the intervention group would be compared to the control group.** This was also a concern for reviewers 1 and 4. The information was incorporated as stated by reviewer # 1 to the section on page 53.

Reviewer # 4

The general comment of this reviewer: "This proposal addresses important aspects of cardiovascular disease- Congestive Heart Failure (CHF). The idea of investigating population of patients at the Grady CHF clinic who often fail to keep their appointments will provide useful information for addressing similar socio-demographic populations elsewhere and thus prevent complications that are associated with CHF. The study aims are well described. Overall project strategies, methodologies, and analyses are well-reasoned but the appropriate methods to accomplish the specific aims of the project are only cursorily described".

The reviewer remarks that the principal investigator is a highly experienced clinician, CHF is of public health significance, and the theoretical models informing the intervention being excellent and well described as a major strength of the project.

Weaknesses mentioned by the reviewer include that many of the contextual variables to be measured are not fully accounted for using innovative statistical methods, and that the **principal investigator has not demonstrated publication record regarding the research topic, and** has never been involved in an NIH-funded intervention study, the list and roles of study personnel are missing in the proposal, as well as the proposed study leadership team to guide intervention. All the comments were taken and included in the proposal. The project will be supported by investigators with strong background on publications in the topic.

Furthermore, the reviewer stated that the **lack of preliminary data regarding the intervention aspects of the study**. There was a study at Grady that showed the high number of no shows in the CHF clinic, and the increased number of readmissions. * **Many statistical methods**

are lacking. This was pointed by reviewers 2 and 3, and the methodology section was modified on page 55.

The **strengths** remarked by the reviewer in the approach section are that the study is built on a well-articulated hypothesis that utilizing theoretical constructs that will help in the control of CHF in at risk populations, the aims are important and could have positive implications for reducing CHF disparity.

APPENDIX 1

NIH R01 Scored Review Criteria_

1. **Significance**.
   Does the project address an important problem or a critical barrier to progress in the field? Is there a strong scientific premise for the project? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

   1 2 3 4 5

Comments:____

2. **Investigator(s)**.
   Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

   1 2 3 4 5

Comments:____

3. **Innovation**.
   Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

1 2 3 4 5

Comments:____

4. Approach.

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility, and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (exclusion) of children, justified in terms of the scientific goals and research strategy proposed?

1 2 3 4 5

Comments:____

5. Environment.

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

1 2 3 4 5

Comments:____

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Chapter V

Grant with incorporated reviewers' critiques

PROJECT SUMMARY/ABSTRACT

Chronic Heart Failure (CHF) is a common medical problem affecting approximately 5.1-5.8 million people in the United States (ACC/AHA 2013, global Health economy 2014, Roger 2013) and about 26 million people worldwide (Ponikowski et al., 2014). It is a chronic and progressive clinical condition in which the heart is not able to meet the body's needs, usually as a consequence of coronary heart disease, long-term hypertension, diabetes, or other baseline heart diseases. It is the most common cause of hospital admissions in the US (Ambrosy et al., 2014).

According to the ACC/AHA, close to 25% of patients hospitalized with CHF are readmitted to the hospital within 30 days (Yancy et al., 2013), and 50% are readmitted in the first 6 months after discharge (Norton, 2011). A large retrospective cohort study in Canada, found that after discharge from Emergency Department (ED) visit, a close follow up (in the first month) by a physician who knows the patient had better outcome than those without follow up, or who were followed by a non-familiar physician (Sidhu et al., 2014). About 30% of patients at the Grady CHF clinic fail to keep their appointments for different reasons (CHF clinic report, 2017). This population of patients would benefit from other options to receive outpatient medical care for their disease and prevent its complications. **The long-term goal** of this study is to improve the management of CHF among patients with frequent no shows in CHF clinic and at high risk of **ED visits, admissions and readmissions to the hospital and poor quality of life (QOL).** This proposal is in response to the National Institute of Health **R01** Program Announcement No. **PA-07-355 for "Improving Heart Failure Disease Management".** We are seeking funding to establish an in-home provider visit program for patients that cannot keep their clinic appointments for psychosocial and/or economic reasons. **The main hypothesis** is that in-home medical visits can help improve the management of CHF in this population, help decrease ED visits, hospitalizations and re-hospitalizations, and improve their quality of life. Our **specific aims** are: **Aim 1-** To identify patients who miss two or more consecutive appointments in the past 6 months at the Grady CHF Clinic. We will review electronic medical records (EMR) and identify patients at high risk, such as those with substance use disorder, frequent no shows, limitations to ambulate or those with 2 or more comorbidities. **Aim 2:** To conduct a focus group in a sample of 6-8 of the identified high-risk patients, to explore the factors affecting their ability to get to the clinic visit, present the proposed program to the participants, learn about how they think the program can help, and some potential barriers for the implementation of the program. **Aim 3:** To perform in-home provider visits to the selected sample of high risk patients for a six-month period and provide them with the regular medical evaluation and plan of care equivalent to a regular visit to the HF clinic. The intervention is **significant** since upon completion of the pilot project we will learn the attitudes and acceptance of the patients toward the program and the challenges that prevent them from being compliant with the clinic visits, will provide medical care to the patients that cannot keep their appointments. In addition, it will prevent these patients from admissions to the hospital and will improve their quality of life. Patients are expected to gradually get reincorporation to the CHF clinic. The study is **innovative** since there is not any specific in-home medical visit program addressing the needs of this population at Grady.

PROJECT NARRATIVE/RELEVANCE:

The proposed study is relevant to public health because heart failure (CHF) is a common chronic disease in the aging population that is increasing in prevalence with a high cost to the Healthcare system. It is the most common cause of hospital admissions; readmissions are now being penalized by the Centers for Medicare and Medicaid Services (CMS), with reimbursement withhold, and they can partially be prevented by improving outpatient care, although those admissions due to disease progression will continue to be challenging to prevent. Providing medical care through an in-home medical visits program for patients that cannot keep their appointments can improve the management of the disease, improve their quality of life, and decrease admissions and readmissions to the hospital.

FACILITIES AND OTHER RESOURCES

This program will utilize one of the offices at the CHF clinic which has been discussed and arranged with the clinic management department. Two desks and two computers with internet access will be provided for the data collection during the visits, as well as office supplies and scales to facilitate patients to keep record of their weight. The team will consist of one cardiologist specialized on CHF, one internist, 2 nurse practitioners with expertise in the CHF management, a pharmacist and one nurse, in addition to a project manager. To prevent the need of hiring new personal, staff from the heart failure clinic has been contacted, and are agreeable to be reassigned to work in the project, including going to the field. The visits will be performed by one of the providers, who will be credentialed to make changes and recommendations such as medication dosage adjustment and or order new prescription/s to the pharmacy. In addition, the provider will be able to check stat potassium, magnesium and creatinine and make medications adjustments based on results. For the home visit, the provider will need a sphygmomanometer, a stethoscope, a pulse oximeter, and a laptop to access epic for immediate documentation. The project is supported by the chief of Cardiology and the Director and Co-Director of the Heart failure clinic at Grady, and by the department of performance improvement. See letters of support in Appendix 4.

SPECIFIC AIMS

Studies conducted by Kim and Han, 2013, have shown that outpatient management strategies have shown to minimize hospital readmission in patients with CHF. Such multidisciplinary interventions can be in clinic or at home**.** Many patients at the Grady CHF clinic are non-adherent to their clinic visits. To close the gap in medical care for those patients, this program will provide in-home medical visits to improve the CHF management of those patients that can provide an address for regular visits. To accomplish the overall goal of this project, we will address the following specific aims:

Aim 1: To identify patients who miss more than two consecutive appointments in the past 6 months at the Grady CHF Clinic by chart review. Electronic medical record (EMR) will be reviewed to identify patients at high risk for missing appointments such as those with substance use disorder, previous number of no shows, limitations to ambulate or those with more than 2 other comorbidities. This proposal hypothesizes that patients with substance use disorder, or limitations to ambulate are at higher risk to miss their appointments and get frequent emergency department (ED) visits and admissions to the hospital.

Aim 2: This aim will randomly select a sample of the identified population at high-risk to miss appointments for conducting a focus group to explore the factors affecting their ability to get to their clinic visits. In addition, the focus group will find out what the participants think about the proposed in-home visit program, how they believe it will help, and will identify potential barriers for the implementation of the program. This aim is based on the hypothesis that getting input from the patient population in study can facilitate the success of the in-home provider visits program, and provide information on how to overcome the specific barriers identified to miss the appointment at the CHF clinic

Aim 3: This aim will perform in-home provider visits to the selected sample of patients with an address (those without an address will be excluded from the study), for a six- month period and provide them with the regular medical evaluation and plan of care equivalent to a regular visit to the CHF clinic. This is based on the hypothesis that providing the in-home provider's visit to patients that are unable to keep their appointments, can prevent them from decompensation of the disease, visits to the ED, getting admitted to the hospital, and improve their health-related quality of life (HRQoL).

IMPACT: Outpatient care through this in-home visit program to patients who miss appointments at the CHF clinic will improve patient's quality of life (QOL) which will be assessed by the NYHA and the Minnesota Quality of Life Questionnaire, a validated questionnaire to be used to assess health related quality of life in a study setting for patients with CHF. The questionnaire will be applied at the beginning and at the end of the intervention. It will help decrease the number of visits to the ED and admissions to the hospital in the CHF clinic population. QOL will be quantified based on visits documented and reported by patients and/or families. This preliminary work could lead to larger scale interventions in this population.

INNOVATION: This will be the first intervention at Grady Memorial Hospital that involves regular provider in-home visits to patients with CHF to provide medical care to those who fail to comply with outpatient follow-up due to medical or community barriers. Readmissions because of poor outpatient management represent a burden to the healthcare system and are used as a CMS quality metric. The overarching long-term goal of the project is to design and implement a patient centered intervention that will improve the management of CHF and decrease hospitalizations among patients who miss their appointments to the Grady CHF clinic by providing in-home visits and facilitating medical care at the patients' home to overcome the identified barriers which lead to missing their clinic visits.

REASEARCH STRATEGY:

A. Background/Significance:

Chronic Heart Failure (CHF) is a very prevalent medical problem, affecting approximately 5.1-5.8 million people in the United States (ACC/AHA 2013, global Health economy 2014, Roger 2013) and about 26 million people worldwide (Ponikowski et al., 2014). Decompensated CHF is the most common cause of hospital admissions (Ambrosy et al., 2014); nearly 25% of patients hospitalized with CHF are readmitted to the hospital within 30 days of discharge (Yancy et al., 2013), and 50% are readmitted in the first 6 months after discharge (Norton et al., 2011). According to the Agency for

Healthcare Research and Quality's Health Care Cost and Utilization Project, appropriate outpatient management is essential to preventing frequent admissions and readmissions to the hospital; the latter is now penalized by the Centers for Medicare & Medicaid services in the form of lower 1-3 % penalty withhold from reimbursements to hospitals with high readmissions rates (CMS). CHF significantly affects the patients and their families' quality of life causing anxiety and depression (Ponikowski et al., 2014) and cause of isolation and a sense of lack of control (Jeon, Kraus, Jowsey, & Glasgow, 2010). Grady Memorial Hospital is a 1000-bed public academic safety-net hospital that delivers medical care to the underserved population of Atlanta. In response to the high volume of yearly admissions for decompensated CHF, in 2011 Grady implemented a CHF program that provides inpatient consultation and transition to follow-up in the CHF clinic within 2 weeks of discharge for every CHF patient admitted in the hospital. The clinic was started by the current director, a Heart failure specialist cardiologist, and is staffed by cardiologists, Internal Medicine physicians, nurse practitioners, and other supportive staff. With a total of 7 providers, the clinic operates 5 days a week (Heart Failure Clinic report, 2017). The patients receive phone call reminders for their appointments and have the option to walk in to the clinic. Despite the very supportive and accessible CHF Clinic at Grady, the no-show rate remains 30-50%. The population at Grady carries several risk factors leading them to miss their appointments placing them at risk of getting clinically decompensated. This causes an increased number of visits to the ED, admissions and readmissions to the hospital, and decreased quality of life. There is a need for an alternative approach to take care of this patient population. The major goal of this project is to develop and implement a program that delivers medical care to patients who are unable to keep their CHF clinic appointments. It will have a public health impact by decreasing the number of hospitalizations, ED visits, and improve compliance to medications, heath related quality of life (HRQoL), and improve the management of the disease in general. The staff for the project will be reassigned from the CHF clinic. This will minimize extra expenses.

Previously, Grady Hospital implemented a Heart Failure Clinic to capture patients referred from the inpatient service for follow up on in the clinic setting once they are discharged from the hospital. Every patient admitted is seen by one member of the CHF clinic team, at least once, and upon discharge follow up is arranged. A large number of patients (30-50%) are unable to attend their clinic visits and are at risk for decompensation. We will base our intervention on **The Belief Health Model (BHM),** and **The Theory of Planned Behavior.** The BHM is a theory of health behavior developed in the 1950's by social psychologists Irvin M. Rosenstock, Godfrey M. Hochbaum, S. Stephen Kegeles, and Howard Leventhal at the US Public Health Services, predicts some health-related behaviors, including behavior related to chronic diseases (Janz & Becker, 1984). It remarks the value-expectancy model, in that primary construct is predicated on the basis that behavior change will occur only when sufficient benefits remain after subtracting the costs (challenges) incurred by performing the behavior". In addition, we will apply **The Theory of Planned Behavior** where the construct is known as the perceived behavior control (Ajzen, 2002). According to this theory, if a behavior is perceived to be important, the individual/family will be more likely to engage in that behavior if they also perceive that it is within their control. Therefore, the proposed program is **significant** from different perspectives:

A1) The program will identify patients at high risk of missing appointments. Identification and analysis of the challenges that prevent these patients from keeping their appointments will be significant to providing medical care based on the individual need/s identified as the potential reason for consistently missing clinic appointments. This program will be significant for patients and their families and will be accepted given the "expected gain of adopting the health -protective behavior" such as compliance with taking the medications as prescribed and adherence to the recommended treatment (ex: nutrition and fluids restriction) as stated by the HBM. This will help with disease control, meaning improvement on the control-MLQF, NYHA Class, reduced unplanned office visits, ED visits and readmissions at the "lower cost of not having to go to the clinic".

A2) The results of the focus groups will enhance the patient's awareness of the benefit of good adherence to treatment, and eventually reincorporate these patients back to the HF clinic. For this purpose, based on the theory of planned behavior, the patient and families that perceive that the better control of heart failure noticed during the in-home visits is the result of their adherence to the medical regimen as prescribed and recommended lifestyle, by perceiving control, patients will learn that the external facilitating factors like the access to clinic and/or transportation to go to the clinic, will provide them with the same benefit, while having more control.

A3) By performing the in-home visits, both theories explained above will make the patients and families entitled to reincorporate to the clinic, and from the hospital, stand point, the program will be significant by decreasing the number of ED visits and admissions to the hospital. On the other hand, by maintaining certain level of disease stability, these patients will have a better quality of life, and may be able to engage in the community.

B) INNOVATION

B1) Our main hypothesis is innovative since this will be the first intervention at Grady Memorial Hospital that involves routine provider in-home visits to CHF patients to provide medical care to those who fail to comply with outpatient follow-ups due to medical or community barriers. The actual CHF program refers patients to an external department for occasional visits but only after the patients have significantly failed to attend the clinic and after several admissions and readmissions to the hospital; it does not provide comprehensive medical care. As the population ages, the prevalence of CHF is projected to increase, with about 10 per 1000 incidence per year after age 65 (Roger, 2012). Our overarching long-term goal is to design and implement a patient centered intervention that will improve the management of CHF and decrease hospitalizations among patients who miss their appointments to the Grady CHF clinic by providing in-home visits and facilitating to overcome the identified barriers which lead to missing their clinic visits.

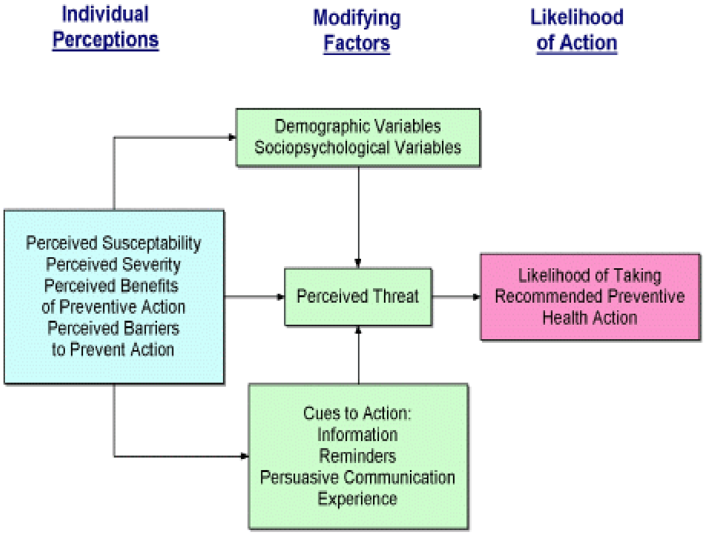
B2) The intervention will be the first initiative at Grady Hospital of medical care provided by regular staff though guaranteeing continuity of care for the CHF population. This modality of medical attention is scalable and can be applied to other chronic diseases in the future.

To prevent the burden of frequent visits to the Emergency Department (ED), frequent hospitalizations and poor quality of life in patients with heart failure, medical institutions have implemented clinics dedicated to follow up on those patients soon after discharge from the hospital to establish regular care for better management of the disease.

C) APPROACH

Based on the previous data, and the high no shows rate (30-50%) at the Heart Failure clinic at Grady, we propose a pilot program that will provide medical care to patients at high risk of missing their appointments by an in-home provider visit. According to a meta-analysis, only about 25% of hospital readmissions within 30 days post discharge can be prevented (van Walraven et al., 2012), and studies have shown that self-care measures such as the lack of early recognition of congestion by the patients, poor knowledge, and non-compliance with treatment are important triggering factors for HF decompensation (Arcand et al., 2011). We hypothesize that providing medical care to this population at home, can improve their quality of life and prevent them from ED visits, and admissions and readmissions to the hospital. We will base our intervention on the following Theoretical Frameworks: The Health Belief Model (HBM) and the Theory of Planned Behavior.

HEALTH BELIEF MODEL

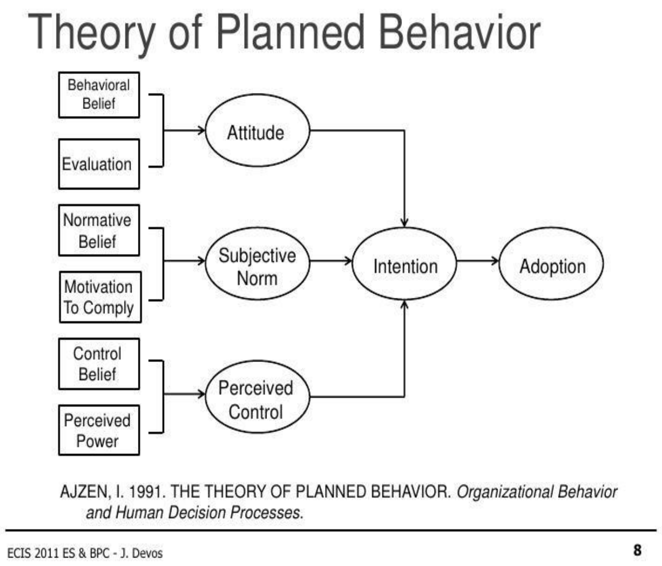


From Simons-Morton, et. al.,(1995). *Introduction to Health Education and Health Promotion, 2nd ed.* Waveland Press

The Health Belief Model (HBM), focuses on the "perceived severity and perceived susceptibility". It tells that the individual should perceive a benefit of the health promotion that outweighs "the cost" of the recommended behavior. Once the person feels susceptible to certain level of threat, under certain psychosocial factors and certain level of information and education, then will be likely to adopt the action. Furthermore, the health promotion should remark the benefits of the suggested health behavior, and at the same time include measures to minimize the barriers. For example, patients with HF should perceive themselves susceptible to the decompensation of the disease and severity of the disabling symptoms such as shortness of breath and its effect on quality of life.

Then they should **perceive** the benefit of adherence to clinic appointments and medical treatment to prevent the harm of the exacerbation/hospitalization with the minimal barriers possible. The three aims for this project are: Aim 1-- identifying patients at high risk followed, Aim 2—running a focus group to assess the perception of disease, barriers to keep clinic visits, and possible benefits of the in-home visit program and, Aim 3- the actual in-home visits for medical care. This program will minimize the costs of hospitalizations, ED visits and readmissions to the hospital, and the challenges for the patients and will help them to experience and perceive the benefit of receiving medical care and an improved quality of life. It will be complemented by applying the Theory of Planned Behavior to add sense of control and eventual reincorporation of the patients to the HF clinic.

The Theory of Planned behavior is based on the perceived behavioral control (Ajzen, 2011). According to this theory, "if a behavior is perceived to be important and subjective norms seem to support the behavior, then people are more likely to engage the behavior if they perceive that is within their control.



AJZEN, I. 1991. THE THEORY OF PLANNED BEHAVIOR. *Organizational Behavior and Human Decision Processes.*

https://www.google.com/search?q=theory+of+planned+behavior+chart&tbm

The perceptions are related to external factors that can be facilitating factors that increase the chance of the behavior, and inhibiting factors, that represent the barriers, while the perceived power of these factors is consider by the individual in the process of adopting the behavior. By experiencing better control of the disease, a sense of worthiness of adherence to therapy, along with education, and the perception of control on the actions to manage their CHF, will trigger the intention of adopting the behavior. In this case, initially adherence to medical recommendations through the in-home visits and eventually reincorporation to the CHF clinic.

C1) INTRODUCTION

Heart failure affects 5.8 million people in the United States (ACC/AHA 2013), and it is the most common cause of hospitalization (Ambrosy et al., 2014). With the better understanding of the pathophysiology and natural history of the disease over the years, contemporarily, the treatment of heart failure involves a multidisciplinary approach that includes outpatient care by a primary care provider, a cardiologist, nurse, pharmacist and other staff for social support, to monitor that patients are on the evidence based medical regimen recommended, and have the education for the proper self-care to reduce complications and hospitalizations (Vaduganathan, Bonow, & Gheorghiade, 2013). Since congestion represents the initial mechanism of decompensation of heart failure, and it can take days to weeks before the individual becomes symptomatic (Gheorghiade et al., 2013), it is important to recognize the early symptoms and signs of congestion to prevent decompensation of the disease. According to a meta-analysis, about 25% of hospital readmissions within 30 days post discharge can be prevented (van Walraven et al., 2012), and studies have shown that poor self-care measures such as the lack of early recognition of congestion by the patients, lack of knowledge, and non-compliance with treatment are important triggering factors for HF decompensation (Arcand et al., 2011).

Importance of ambulatory management for patients with Chronic Heart Failure- The management of heart failure involves an evidence based medical regimen as well as several lifestyle related actions. Hence, the involvement of the patient and family are essential in this process for a good control of the disease. Riegel and Moser, 2013 defined self-care in heart failure as "positive behaviors leading to decisions and actions that an individual can take to help maintain clinical stability and cope with the disease". Given that the patient lifestyle is determinant for the self-care education, their habitat has been a recommendable environment for the process of education, ambulatory care of patients with CHF has been a target of study as an intervention to explore its effect on the management of the disease (Mussi et al., 2013). In addition, according to a randomized controlled clinical trial to evaluate the effectiveness of an educational program in nursing, such as educational meetings and home visits, Rodriguez (2012) found that the educational intervention was beneficial on the self-care of patients with heart failure (Rodriguez-Gazquez Mde et al., 2012). This concept may apply to patients who cannot follow up in clinic for different reasons, and this program aims to provide medical care to these patients that is equivalent to regular clinic visits

Challenges for patients to keep clinic appointments and risk factors to miss clinic appointments- No results on our search review showed studies on the challenges or factors associated with missing appointments with CHF patients specifically. A telephone survey conducted at on patients who had "no show" at the Grady CHF clinic in 2015, revealed financial issues and transportation as the two most common reported reasons by patients to miss their clinic appointments. A study showed race and income as significantly related factors to missing clinic appointments (Miller et al., 2015). The study was conducted in an otolaryngology clinic in Detroit, and although it was performed in a different specialty clinic, the socio-economic factors studied can be validated to populations with similar financial challenges.

Consequences of missing clinic appointments- Getting evidence-based therapy and the necessary adjustments by a regular provider can help to improve survival and decrease Page **hospitalizations** and readmissions in patients with CHF (Vaduganathan et al., 2013). Patients who fail to keep their clinic appointments lack the continuity of care, and therefore, are at higher risk for increased visits to the ED, hospitalizations and readmissions, and decreased quality of life. Continuity of care soon after the hospitalization can improve patient's outcomes. According to a systematic review conducted by Case et al (2010) on six studies related to heart failure management revealed that all the studies demonstrated decreased readmissions in patients who participated in a heart failure management program by a clinical registered nurse. In addition, a retrospective study (Punchik et al., 2017) found that home care for homebound patients with CHF reduces healthcare service utilization and overall cost. The comparison of a six-month pre-visit vs that home visit period showed a decrease in hospitalization and ED visit by almost 50% (47% and 46% respectively) as well as a 67% decrease in length of stay for CHF, and 24% overall costs reduction (Punchik et al., 2017).

Grady CHF Clinic and its challenges- According to the Grady CHF Quality Metrics report, in 2016, although 87% of the patients discharged from the hospital received the follow up phone call, only 37% adhered to a follow up visit within 7 days of discharge or less. The CHF clinic at Grady offers substantial services to the patients, and despite the accessibility, the no show rate remains high, and patients continue to get frequently admitted and readmitted to the hospital. An intervention that provides evidence based medical care to those patients can improve their quality of life, decrease visits to the ED and hospitalizations. A randomized clinical trial of provider home visits and phone calls on patients after hospitalization for decompensated heart failure showed improved knowledge and self-management of the disease (Mussi et al., 2013). This trial partially confirmed the results of a small study performed by Aguado (2010) which had shown that provider home visits for education can help decrease readmissions, visits to the ED, and healthcare costs in general (Aguado et al., 2010).

C2) PELIMINARY STUDIES

Provider in-home visits in patients with chronic diseases and heart failure - In an attempt to keep patients with chronic diseases with the optimum possible quality of life and prevent visits to the Emergency Department and reduce hospitalizations, researchers have studied several interventions in the outpatient setting such as structured outpatient clinic with cardiologist, nurses, and telephone follow up by clinician within 72 hours of hospital discharge and regular visits. In-home visits an intervention that has been found to help provide medical care to patients who are unable to keep up with their visits to the clinic. A systematic review showed that home care can improve the outcomes in patients with chronic disease who cannot go to their clinics and improve their functional status (Health Quality Ontario, 2013). Castro and Ilksoy, 2015 conducted a survey at Grady that showed a high rate of no show, and several socioeconomic factors to be the reason for the no shows to the CHF clinic visits.

The telephone survey revealed forgetfulness, lack of reminder or scheduling errors as the main reasons to miss appointments, followed by transportation and financial issues. These results were based on the 40% of 145 patients attempted to reach, since 60% were not reachable by phone after 3 attempts. This shows a lack of stability on how to locate patients for appointments arrangements. There has not been any study at Grady Hospital, or in the state of Georgia that investigates in-home medical visits for patients with heart failure. In-home provider visits can help with the barrier to deliver medical care to the study population.

Overall, preliminary studies demonstrate that in-home visits for patients that have challenges to adhere to their clinic appointments can reduce the number of visits to the ED, reduce **admissions** and readmissions to the hospital, improve quality of life, and improve disease management. Although there has not been any research at Grady, a survey reports financial constraints as the most common reason for missed appointments.

C 3) RESEARCH PLAN

Study Design and Method: To address gaps in care for CHF patients at high risk of missing their appointments at the Grady CHF clinic, we propose to retrospectively identify and statistically determined sample of patients at risk of missing appointments followed by focus groups among patients, and then the prospective pilot of the in-home medical visits program to those enrolled in the study.

Aim 1: To identify patients who miss two or more consecutive appointment at the Grady CHF Clinic by chart review. Rationale: By identifying patients at high risk, we will target the population that is more likely to get admitted to the hospital and need to visit the ED for medical care. Hypothesis: Patient with uncontrolled mental illness, substance abuse or other comorbidities are at higher risk of missing their appointments and getting frequent ED visits and admissions to the hospital. Contact information will also be obtained from medical records to contact the patients to offer the initial provider visit and participation in the study. See Appendix XX for script for invitation call and letter. Design: To accomplish this aim we will review electronic medical records (EMR) and identify patients at high risk. The patients will be considered at high risk if they have missed two or more consecutive appointments at the CHF clinic in the past six months. Other inclusion criteria include: - Being within the age 45 and above with a diagnosis of CH, having a documented psychiatric diagnosis, having a substance abuse diagnosis, having two or more other comorbidities documented such as diabetes, coronary artery disease, chronic kidney disease stage III or above, chronic liver disease, 2 or more unplanned office visits, having one visit to the ED, and being readmitted to the hospital within one month of the missed appointment. Patients without an address and with a diagnosis of cancer will be excluded, since they are more likely to be getting some type of home care assistance. Once the population size (N or total number of patients who missed 2 or more appointments) is extracted from

medical records, the sample size will be calculated based on the statistic formula using a margin of error of 0.5 and 95% of confidence interval.
Expected Outcomes: the implementation of the in-home provider visits will decrease hospital admissions and readmission, as well as the frequency of ED visits of patients who are unable to keep their clinic appointments at the Grady Hear Failure clinic.

Data analysis for Aim 1: The data obtained from the chart review will be analyzed by innovative statistic methods, and the results will be synthesized in tables and graphs. We will determine the correlation between missing appointments and ED visits and hospitalizations, as well as the demographics of the studied population.

Expected Outcomes: The proposal will perfectly target those patients and provide them with the medical care needed to improve disease control by preventing them from recurrent ED visits and hospitalizations and improve their quality of life as measured by a MLQF and lower NHYA class.
The results will be compared with a random control group of same number of patients in similar conditions that meet the inclusion criteria and are not enrolled in the program.

Potential Problems and Alternatives:
For this initial part of the project, we anticipate some difficulties on **reaching out the patients**. Based on our survey in 2015 on exploring reasons to miss appointments, we were unable to contact about 50% of the patients due to non-working phones in the system. We will start by contacting the phones in the system and then sending a letter. We will make attempts until we recruit a few more patients above the calculated sample to ensure a final sample size that is representative of at population in study. Once patients are enrolled, retention can be a problem. The program will facilitate the visit schedule in a way that the patients report to be the most convenient for them and will also keep open communication on the phone with patients and 1-2 family members that they authorize for some needed recommendations in between visits. The lack of time represents another barrier for providers with already multiple tasks in the hospital and clinic. Another possible challenge is to have the need to hire more staff to the clinic if the redistribution of personal is not enough to perform the visits, or they are needed to be back in the CHF clinic.

Aim 2: Running a focus group of 6-8 patients to explore on the factors affecting their ability to get to the clinic visits, and ask participants about the proposed in-home visit program, exploring how they think the program may help and discuss some potential barriers for the implementation of the program. Rationale: Obtaining data directly from patients about their perception of the CHF condition, and study will increase the chance for them to engage in the study and develop the sense of control and changed behavior. Hypothesis: Getting input from the patient population at risk of missing appointments in the heart failure clinic can facilitate the success of the in-home provider visits and overcoming the specific barriers identified to miss the appointment. Experimental design: To accomplish this aim, we will choose the first 6-8 patients that are representative of sex, different ages, and agree to participate in the project, and after obtaining written consent and performing the screening visit with the intake questionnaire, we will arrange for a focus group to explore the challenges that patients face to keep up with their CHF clinic appointments and treatments, how they believe those challenges can be addressed, their insight and perception of the proposed program for the patients, how they think a program like this can help, and the barriers they expect during the provider in-home visits.

Data analysis for Aim 2: The information obtained from the focus group will be transcribed for analysis. Then, it will be summarized in a matrix table for the information of the data and determine the level of consensus of the focus group.
Expected Outcomes: According to our hypothesis, the focus groups results will reveal the actual barriers for this patient population to adhere to their CHF clinic appointments and taking their medications, it will also reveal possible challenges to the implementation of the program.

Potential Problems and Alternatives. Once the patients agree to participate in the focus group, the main problem that we expect is that patients may have difficulties getting to the hospital for the focus group. We will provide a round trip MARTA card to address that barrier.

Specific Aim 3: To perform in-home provider visits to the patients selected for a six-month period and provide them with the regular medical evaluation and plan of care equivalent to a regular visit to the CHF clinic. Rationale: Based on the HBM and the theory of planned behavior, patients who can identify and perceive gain compared with the challenges, identify the facilitating and inhibiting external factors, and perceive a sense of control, are more likely to engage in the behavior. Hypothesis: Providing the in-home medical visit to patients who are unable to keep their appointments can prevent them from decompensation of the disease, visits to the ED, getting admitted to the hospital, and improve their HRQoL. Design: This aim will be addressed by performing the actual provider's visit once consent is obtained. A validated pre-intervention form to assess quality of life (QOL) will be completed at the initial visit. Other elements of the visit will include exploring symptoms, reviewing, adjusting and prescribing new medications if needed, conduct a physical exam, and draw blood work if indicated. Patients enrolled in the home visit program will be supplied with the same educational material provided to patients by the CHF clinic and will be scheduled for a follow-up in the clinic or at home according to their medical need. During the same time, the QOL questionnaire and the form to identify barriers to miss appointment will be applied to a control group of patients with similar risk factors that will not be enrolled in the study at the pre and post intervention. The identified barriers to keep appointments by the survey will be addressed by getting patients referred to the services needed. Patients will be placed on a list in the EMR to keep records of hospitalizations.
Analysis for aim 3: After 6 months, a post-intervention QOL questionnaire will be applied after obtaining written consent, as well as their perception on overcoming barriers of missing appointments to both groups and will compare to the control group that has not received the provider's visit. Most of the studies on in-home visits for patients with heart failure have been performed by nurses on patients that are homebound, and they include sporadic support visits less than a regular provider's home visit.
Expected Outcomes: If our hypothesis is supported, we expect that patients enrolled in the study will have less admissions to the hospital and ED visits than the controls and will show improvement in their QOL and reincorporate to back to the clinic.

Protection of Human Subjects- an Institutional Review Board (IRB) exemption letter was obtained and subsequently presented to the Performance Improvement Department at Grady Memorial Hospital for their approval.

OVERALL SUMMARY AND CONCLUSION- We believe this study will allow us to offer a feasible option to provide medical care that is patient centered in the vulnerable CHF population at high risk. The literature supports that benefit of in-home medical visits for patients missing scheduled appointments and at high risk for complications. This study will have significant impact on the CHF population and the model could be used for other chronic diseases.

References

Aguado, O., Morcillo, C., Delas, J., Rennie, M., Bechich, S., Schembari, A., . . . Rosell, F. (2010). Long-term implications of a single home-based educational intervention in patients with heart failure. *Heart Lung, 39*(6 Suppl), S14-22. doi:10.1016/j.hrtlng.2010.04.010

Ajzen, I. (2011). The theory of planned behaviour: reactions and reflections. *Psychol Health, 26*(9), 1113-1127. doi:10.1080/08870446.2011.613995

Ambrosy, A. P., Fonarow, G. C., Butler, J., Chioncel, O., Greene, S. J., Vaduganathan, M., . . . Gheorghiade, M. (2014). The global health and economic burden of hospitalizations for heart failure: lessons learned from hospitalized heart failure registries. *J Am Coll Cardiol, 63*(12), 1123-1133. doi:10.1016/j.jacc.2013.11.053

Arcand, J., Ivanov, J., Sasson, A., Floras, V., Al-Hesayen, A., Azevedo, E. R., . . . Newton, G. E. (2011). A high-sodium diet is associated with acute decompensated heart failure in ambulatory heart failure patients: a prospective follow-up study. *Am J Clin Nutr, 93*(2), 332-337. doi:10.3945/ajcn.110.000174

Centers for Medicare and Medicaid Services (CMS) Obtained from:
https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Readmissions-Reduction-Program.html

Gheorghiade, M., Vaduganathan, M., Fonarow, G. C., & Bonow, R. O. (2013). Rehospitalization for heart failure: problems and perspectives. *J Am Coll Cardiol, 61*(4), 391-403. doi:10.1016/j.jacc.2012.09.038

Janz, N. K., & Becker, M. H. (1984). The Health Belief Model: a decade later. *Health Educ Q, 11*(1), 1-47. doi:10.1177/109019818401100101

Jeon, Y. H., Kraus, S. G., Jowsey, T., & Glasgow, N. J. (2010). The experience of living with chronic heart failure: a narrative review of qualitative studies. *BMC Health Serv Res, 10*, 77. doi:10.1186/1472-6963-10-77

Miller, A. J., Chae, E., Peterson, E., & Ko, A. B. (2015). Predictors of repeated "no-showing" to clinic appointments. *Am J Otolaryngol, 36*(3), 411-414. doi:10.1016/j.amjoto.2015.01.017

Mussi, C. M., Ruschel, K., de Souza, E. N., Lopes, A. N., Trojahn, M. M., Paraboni, C. C., & Rabelo, E. R. (2013). Home visit improves knowledge, self-care and adhesion in heart failure: Randomized Clinical Trial HELEN-I. *Rev Lat Am Enfermagem, 21 Spec No*, 20-28.

Norton, C., Georgiopoulou, V. V., Kalogeropoulos, A. P., & Butler, J. (2011). Epidemiology and cost of advanced heart failure. *Prog Cardiovasc Dis, 54*(2), 78-85. doi:10.1016/j.pcad.2011.04.002

Ponikowski, P., Anker, S. D., AlHabib, K. F., Cowie, M. R., Force, T. L., Hu, S., . . . Filippatos, G. (2014). Heart failure: preventing disease and death worldwide. *ESC Heart Fail, 1*(1), 4-25. doi:10.1002/ehf2.12005

Punchik, B., Komarov, R., Gavrikov, D., Semenov, A., Freud, T., Kagan, E., . . . Press, Y. (2017). Can home care for homebound patients with chronic heart failure reduce hospitalizations and costs? *PLoS One, 12*(7), e0182148. doi:10.1371/journal.pone.0182148

Rodriguez-Gazquez Mde, L., Arredondo-Holguin, E., & Herrera-Cortes, R. (2012). Effectiveness of an educational program in nursing in the self-care of patients with heart failure: randomized controlled trial. *Rev Lat Am Enfermagem, 20*(2), 296-306.

Sidhu, R. S., Youngson, E., & McAlister, F. A. (2014). Physician continuity improves outcomes for heart failure patients treated and released from the emergency department. *JACC Heart Fail, 2*(4), 368-376. doi:10.1016/j.jchf.2014.03.006

Vaduganathan, M., Bonow, R. O., & Gheorghiade, M. (2013). Thirty-day readmissions: the clock is ticking. *JAMA, 309*(4), 345-346. doi:10.1001/jama.2012.205110 van Walraven, C., Jennings, A., & Forster, A. J. (2012). A meta-analysis of hospital 30-day avoidable readmission rates. *J Eval Clin Pract, 18*(6), 1211-1218. doi:10.1111/j.1365-2753.2011.01773.x

Yancy, C. W., Jessup, M., Bozkurt, B., Butler, J., Casey, D. E., Jr., Drazner, M. H., . . . American Heart Association Task Force on Practice, G. (2013). 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol, 62*(16), e147-239. doi:10.1016/j.jacc.2013.05.019

Improving Management of Chronic Heart Failure

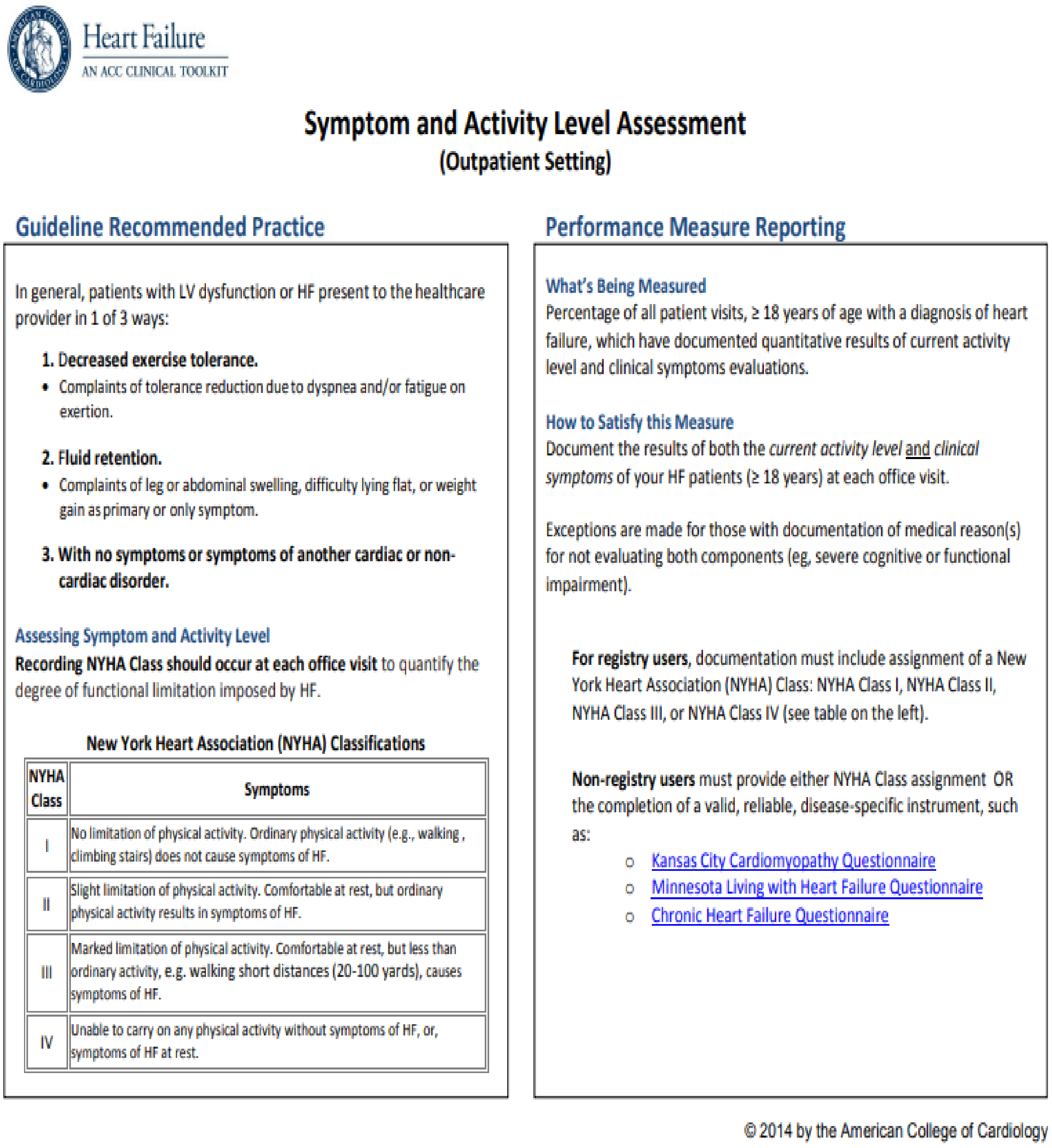
Appendix 1- The New York Heart Association symptomatic assessment instrument

Appendix 2- The Minnesota Living with Heart Failure Questionnaire

Appendix 3- IRB Exemption letter

Appendix 4- Letters of Support

Appendix 5 – Consent to participate in intervention



Heart Failure
AN ACC CLINICAL TOOLKIT

Symptom and Activity Level Assessment

(Outpatient Setting)

Guideline Recommended Practice

In general, patients with LV dysfunction or HF present to the healthcare provider in 1 of 3 ways:

1. **Decreased exercise tolerance.**
   - Complaints of tolerance reduction due to dyspnea and/or fatigue on exertion.
2. **Fluid retention.**
   - Complaints of leg or abdominal swelling, difficulty lying flat, or weight gain as primary or only symptom.
3. **With no symptoms or symptoms of another cardiac or non-cardiac disorder.**

Assessing Symptom and Activity Level

Recording NYHA Class should occur at each office visit to quantify the degree of functional limitation imposed by HF.

New York Heart Association (NYHA) Classifications

NYHA Class	Symptoms
I	No limitation of physical activity. Ordinary physical activity (e.g., walking, climbing stairs) does not cause symptoms of HF.
II	Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in symptoms of HF.
III	Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity, e.g. walking short distances (20-100 yards), causes symptoms of HF.
IV	Unable to carry on any physical activity without symptoms of HF, or, symptoms of HF at rest.

Performance Measure Reporting

What's Being Measured

Percentage of all patient visits, ≥ 18 years of age with a diagnosis of heart failure, which have documented quantitative results of current activity level and clinical symptoms evaluations.

How to Satisfy this Measure

Document the results of both the *current activity level* and *clinical symptoms* of your HF patients (≥ 18 years) at each office visit.

Exceptions are made for those with documentation of medical reason(s) for not evaluating both components (eg, severe cognitive or functional impairment).

For registry users, documentation must include assignment of a New York Heart Association (NYHA) Class: NYHA Class I, NYHA Class II, NYHA Class III, or NYHA Class IV (see table on the left).

Non-registry users must provide either NYHA Class assignment OR the completion of a valid, reliable, disease-specific instrument, such as:

- Kansas City Cardiomyopathy Questionnaire
- Minnesota Living with Heart Failure Questionnaire
- Chronic Heart Failure Questionnaire

MINNESOTA LIVING WITH HEART FAILURE® QUESTIONNAIRE

The following questions ask how much your heart failure (heart condition) affected your life during the past month (4 weeks). After each question, circle the 0, 1, 2, 3, 4 or 5 to show how much your life was affected. If a question does not apply to you, circle the 0 after that question.

Did your heart failure prevent you from living as you wanted during the past month (4 weeks) by -	**No**	**Very Little**				**Very Much**
1. causing swelling in your ankles or legs?	0	1	2	3	4	5
2. making you sit or lie down to rest during the day?	0	1	2	3	4	5
3. making your walking about or climbing stairs difficult?	0	1	2	3	4	5
4. making your working around the house or yard difficult?	0	1	2	3	4	5
5. making your going places away from home difficult?	0	1	2	3	4	5
6. making your sleeping well at night difficult?	0	1	2	3	4	5
7. making your relating to or doing things with your friends or family difficult?	0	1	2	3	4	5
8. making your working to earn a living difficult?	0	1	2	3	4	5
9. making your recreational pastimes, sports or hobbies difficult?	0	1	2	3	4	5
10. making your sexual activities difficult?	0	1	2	3	4	5
11. making you eat less of the foods you like?	0	1	2	3	4	5
12. making you short of breath?	0	1	2	3	4	5
13. making you tired, fatigued, or low on energy?	0	1	2	3	4	5
14. making you stay in a hospital?	0	1	2	3	4	5
15. costing you money for medical care?	0	1	2	3	4	5
16. giving you side effects from treatments?	0	1	2	3	4	5
17. making you feel you are a burden to your family or friends?	0	1	2	3	4	5
18. making you feel a loss of self-control in your life?	0	1	2	3	4	5
19. making you worry?	0	1	2	3	4	5
20. making it difficult for you to concentrate or remember things?	0	1	2	3	4	5
21. making you feel depressed?	0	1	2	3	4	5

Program Director/Principal Investigator (Last, First, Middle): Castro-Revoredo, Iris A.

DETAILED BUDGET FOR INITIAL BUDGET PERIOD	FROM	THROUGH
Improving Management of Chronic Heart Failure	03/5/2019	03/4/2020

List PERSONNEL Emory University/Grady Memorial Hospital
Use Cal, Acad, or Summer to Enter Months Devoted to Project
Enter Dollar Amounts Requested *(omit cents)* for Salary Requested and Fringe Benefits

NAME	ROLE ON PROJECT	Cal. Months	Acad. Months	Summer Months	INST.BASE SALAR	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
Iris Castro-Revoredo	PD/PI	12				40,000.00	200.00	40,200.00
Modele Ogunniyi	Cardiologist	6				25,000.00	200.00	25,200.00
Anekwe Onwuanyi	CHF cardiologist	6				25,000.00	200.00	25,200.00
Smith, Samantha	Manager	12				25,000.00	200.00	20,200.00
Jones, Pat	NP	12				20,000.00	200.00	20,200.00
Brown, Eddie	SW	12				20,000.00	200.00	20,200.00
Perez, Crystal	Pharm D	12				25,000.00	200.00	30,200.00
SUBTOTALS →						$180,000.00	$1,400.00	$181,400.00

CONSULTANT COSTS $10,000.00	$10,500.00
EQUIPMENT *(Itemize)* 3 stat lab machines x $6,000 $18,000.00 30 scales x $50.00= $1,500.00 3 Sphygmomanometers and 3 stethoscopes x $200 = $600.00	$20,100.00
SUPPLIES *(Itemize by category)* 2 desktop computers x $1,000.00 = $2,000.00 3 laptops x $750.00 $2,250.00 Office supplies------------- $ 2,250.00	$5,500.00
TRAVEL Home visits	$7,500.00
INPATIENT CARE COSTS $8,000.00	$8,000.00
OUTPATIENT CARE COSTS $6,000.00	$6,000.00
ALTERATIONS AND RENOVATIONS *(Itemize by category)* $10,000.00	$10,000.00
OTHER EXPENSES *(Itemize by category)*	

CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS	$250,000.00
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 7a, Face Page)*		**$ 250,000.00**
CONSORTIUM/CONTRACTUAL COSTS	FACILITIES AND ADMINISTRATIVE COSTS	13,550.00
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD		**$ 263,550.00**

PHS 398 (Rev. 01/18 Approved Through 03/31/2020)
OMB No. 0925-0001 Page ____ **Form Page 4**

Letter of Intitututional Support

Institutional Review Board (IRB) Exemption letter

OMB No. 0925-0001 and 0925-0002 (Rev. 10/15 Approved Through 10/31/2018)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: **Castro-Revoredo, Iris Altagracia**

eRA COMMONS USER NAME (credential, e.g., agency login): icastro

POSITION TITLE: Assistant Professor of Medicine, Division of General Medicine and Geriatrics at Emory University

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Universidad Autonoma de Santo Domingo (UASD)	MD	07/28/1989	Doctor in Medicine
Mount Sinai School of Medicine/North General Hospital	Internal Medicine residency	06/30/2001	Internal Medicine
Emory University- Rollins School of Public Health	MPH	Summer 2018	Preventive Science

A. Personal Statement

I have the background and experience of working with a multicultural immigrant population and teaching medical residents about weight and its associated complications such as metabolic syndrome. During my career I have develop the clinical skills of working with a diverse population and I have become interested on the disparity of chronic diseases and access of care in the populations with chronic heart failure. As a junior investigator, the motivation to work with the Heart Failure Clinic team at Grady, makes me confident that my expertise in the field will allow to make a significant contribution to the study to develop an in-home provider visit program that will prompt and support the medical care for those who are not able to keep up with appointments to the Heart Failure clinic and the subsequent behavioral change to prevent visits to the ED and admissions to the hospital.

The high prevalence of CHF and its consequences has become one of the areas that has taken my attention by the most over the years. As a clinician I have been following the literature closely, and now, in the transition of expanding my work to impact a much larger population through the implementation of this project.

Improving Management of Chronic Heart Failure

The prevalence of CHF and its physical and psychosocial implications, more remarkable as the aging population grows, makes it necessary to develop interventions that facilitate providing medical care to the patients in a home environment to improve their quality of life.

As a junior investigator, I will be working with Drs. Onwuanyi and Ogunniyi as main collaborators. Dr. Onwuanyi has a broad background as a Cardiologist and research methods, in addition of being the author of the foundation of the CHF Clinic at Grady, with specific training in CHF, and expertise in key research areas of this application. He is the Chief of Cardiology for Morehouse School of Medicine, he is recognized nationally as a best practice leader and director of the Heart Failure Clinic at Grady Hospital. He has several publications in CHF in peer-reviewed journals. Dr. Modele Ogunniyi, Associate Professor of Cardiology at Emory University, is the Co-Director of the Heart Failure Clinic at Grady Memorial Hospital will provide the support as field advisor for the concretization of this project.

In summary, I am a junior investigator with a long clinical experience managing chronic diseases such as CHF in socioeconomic challenged populations, now in process of developing in the research and interested in interventions that aim to improve disease management and quality of life in patients with CHF that are not able to attend their clinic appointments.

B. Positions and Honors.

Positions and Employment

1998-2001	Post Graduate Residency training in Internal Medicine, Mount Sinai University/North General Hospital, New York, NY
2001-2006	Internal Medicine in Center for Detox from Alcohol and Substance abuse, Pan American Medical Center, New York, NY
2002-2006	Assistant Professor of General Medicine, Champion on Diabetes care initiative. Columbia University, New York, NY
2006-Present	Assistant Professor, Department of General Medicine, Emory University-Grady Memorial Hospital

Other Experience and Professional Memberships

2010-present	Member, American College of Physicians
2011-present	Member, Society of General Internal Medicine
2010-Present	Member, National Hispanic Medical Society

Contribution to Science

I have dedicated my career to mostly clinical work in the inpatient and outpatient setting, as well as academics, participating in the training of over 10 cohorts of Internal Medicine residents and students. I am currently working on a study to analyze the variance on the frequency that providers see their patients in primary care, and its implications in the control of hypertension and diabetes, and in overutilization of the resources in clinics. I am completing my master's in public health, and I am on the process to developing some projects on Health Services Research in primary care.

References

Achil, I., Zanini, A., Gattesco, D., & Palese, A. (2013). [What criteria are used by home care nurses to decide about frequency of home visits in the follow-up of patients with heart failure?]. *Ig Sanita Pubbl, 69*(2), 195-207.

Aguado, O., Morcillo, C., Delas, J., et al. (2010). Long-term implications of a single home-based educational intervention in patients with heart failure. *Heart Lung, 39*(6 Suppl), S14-22. doi:10.1016/j.hrtlng.2010.04.010

Ajzen, I. (2011). The theory of planned behaviour: reactions and reflections. *Psychol Health, 26*(9), 1113-1127. doi:10.1080/08870446.2011.613995

Ambrosy, A. P., Fonarow, G. C., Butler, J., et al. (2014). The global health and economic burden of hospitalizations for heart failure: lessons learned from hospitalized heart failure registries. *J Am Coll Cardiol, 63*(12), 1123-1133. doi:10.1016/j.jacc.2013.11.053

Anderson, M. A., Levsen, J., Dusio, M. E., et al. (2006). Evidenced-based factors in readmission of patients with heart failure. *J Nurs Care Qual, 21*(2), 160-167.

Annema, C., Luttik, M. L., & Jaarsma, T. (2009). Reasons for readmission in heart failure: Perspectives of patients, caregivers, cardiologists, and heart failure nurses. *Heart Lung, 38*(5), 427-434. doi:10.1016/j.hrtlng.2008.12.002

Arcand, J., Ivanov, J., Sasson, A., et al. (2011). A high-sodium diet is associated with acute decompensated heart failure in ambulatory heart failure patients: a prospective follow-up study. *Am J Clin Nutr, 93*(2), 332-337. doi:10.3945/ajcn.110.000174

Bui, A. L., Horwich, T. B., & Fonarow, G. C. (2011). Epidemiology and risk profile of heart failure. *Nat Rev Cardiol, 8*(1), 30-41. doi:10.1038/nrcardio.2010.165

Butler, J., Kalogeropoulos, A., Georgiopoulou, V., et al. (2008). Incident heart failure prediction in the elderly: the health ABC heart failure score. *Circ Heart Fail, 1*(2), 125-133. doi:10.1161/CIRCHEARTFAILURE.108.768457

Carson, P., Tognoni, G., & Cohn, J. N. (2003). Effect of Valsartan on hospitalization: results from Val-HeFT. *J Card Fail, 9*(3), 164-171. doi:10.1054/jcaf.2003.22

DeVore, A. D., Hammill, B. G., Sharma, P. P., et al. (2014). In-hospital worsening heart failure and associations with mortality, readmission, and healthcare utilization. *J Am Heart Assoc, 3*(4). doi:10.1161/JAHA.114.001088

Dunbar, S. B., Reilly, C. M., Gary, R., et al. (2015). Randomized clinical trial of an integrated self-care intervention for persons with heart failure and diabetes: quality of life and physical functioning outcomes. *J Card Fail, 21*(9), 719-729. doi:10.1016/j.cardfail.2015.05.012

Eastwood, C. A., Quan, H., Howlett, J. G., & King-Shier, K. M. (2017). Factors Associated With 7-Day Rehospitalization After Heart Failure Admission. *J Cardiovasc Nurs, 32*(4), 339-347. doi:10.1097/JCN.0000000000000347

Echeverry, L. M., Lamb, K. V., & Miller, J. (2015). Impact of APN Home Visits in Reducing Healthcare Costs and Improving Function in Homebound Heart Failure. *Home Healthc Now, 33*(10), 532-537. doi:10.1097/NHH.0000000000000304

Fergenbaum, J., Bermingham, S., Krahn, M., Alter, D., & Demers, C. (2015). Care in the Home for the Management of Chronic Heart Failure: Systematic Review and Cost-Effectiveness Analysis. *J Cardiovasc Nurs, 30*(4 Suppl 1), S44-51. doi:10.1097/JCN.0000000000000235

Fonarow, G. C., Albert, N. M., Curtis, A. B., et al. (2010). Improving evidence-based care for heart failure in outpatient cardiology practices: primary results of the Registry to Improve the Use of Evidence-Based Heart Failure Therapies in the Outpatient Setting (IMPROVE HF). *Circulation, 122*(6), 585-596. doi:10.1161/CIRCULATIONAHA.109.934471

Fowler, M. B., Vera-Llonch, M., Oster, G., et al. (2001). Influence of carvedilol on hospitalizations in heart failure: incidence, resource utilization and costs. U.S. Carvedilol Heart Failure Study Group. *J Am Coll Cardiol, 37*(6), 1692-1699.

Gheorghiade, M., Vaduganathan, M., Fonarow, G. C., & Bonow, R. O. (2013). Rehospitalization for heart failure: problems and perspectives. *J Am Coll Cardiol, 61*(4), 391-403. doi:10.1016/j.jacc.2012.09.038

Go, A. S., Mozaffarian, D., Roger, V. L., et al. (2013). Heart disease and stroke statistics--2013 update: a report from the American Heart Association. *Circulation, 127*(1), e6-e245. doi:10.1161/CIR.0b013e31828124ad

Goldstein, N. E., May, C. W., & Meier, D. E. (2011). Comprehensive care for mechanical circulatory support: a new frontier for synergy with palliative care. *Circ Heart Fail, 4*(4), 519-527. doi:10.1161/CIRCHEARTFAILURE.110.957241

Hauptman, P. J., Rich, M. W., Heidenreich, P. A., et al. (2008). The heart failure clinic: a consensus statement of the Heart Failure Society of America. *J Card Fail, 14*(10), 801-815. doi:10.1016/j.cardfail.2008.10.005

Heidenreich, P. A., Albert, N. M., Allen, L. A., et al. (2013). Forecasting the impact of heart failure in the United States: a policy statement from the American Heart Association. *Circ Heart Fail, 6*(3), 606-619. doi:10.1161/HHF.0b013e318291329a

Howlett, J. G. (2014). Specialist heart failure clinics must evolve to stay relevant. *Can J Cardiol, 30*(3), 276-280. doi:10.1016/j.cjca.2013.12.022

Hunt, S. A., Abraham, W. T., Chin, M. H., et al. (2009). 2009 Focused update incorporated into the ACC/AHA 2005 Guidelines for the Diagnosis and Management of Heart Failure in Adults A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines Developed in Collaboration With the International Society for Heart and Lung Transplantation. *J Am Coll Cardiol, 53*(15), e1-e90. doi:10.1016/j.jacc.2008.11.013

Janz, N. K., & Becker, M. H. (1984). The Health Belief Model: a decade later. *Health Educ Q, 11*(1), 1-47. doi:10.1177/109019818401100101

Jeon, Y. H., Kraus, S. G., Jowsey, T., & Glasgow, N. J. (2010). The experience of living with chronic heart failure: a narrative review of qualitative studies. *BMC Health Serv Res, 10*, 77. doi:10.1186/1472-6963-10-77

Lloyd-Jones, D., Adams, R. J., Brown, T. M., et al. (2010). Executive summary: heart disease and stroke statistics--2010 update: a report from the American Heart Association. *Circulation, 121*(7), 948-954. doi:10.1161/CIRCULATIONAHA.109.192666

Markle-Reid, M., Browne, G., & Gafni, A. (2013). Nurse-led health promotion interventions improve quality of life in frail older home care clients: lessons learned from three randomized trials in Ontario, Canada. *J Eval Clin Pract, 19*(1), 118-131. doi:10.1111/j.1365-2753.2011.01782.x

Maru, S., Byrnes, J., Carrington, M. J., et al. (2015). Cost-effectiveness of home versus clinic-based management of chronic heart failure: Extended follow-up of a pragmatic, multicentre randomized trial cohort - The WHICH? study (Which Heart Failure Intervention Is Most Cost-Effective & Consumer Friendly in Reducing Hospital Care). *Int J Cardiol, 201*, 368-375. doi:10.1016/j.ijcard.2015.08.066

McAlister, F. A., Stewart, S., Ferrua, S., & McMurray, J. J. (2004). Multidisciplinary strategies for the management of heart failure patients at high risk for admission: a systematic review of randomized trials. *J Am Coll Cardiol, 44*(4), 810-819. doi:10.1016/j.jacc.2004.05.055

Miller, A. J., Chae, E., Peterson, E., & Ko, A. B. (2015). Predictors of repeated "no-showing" to clinic appointments. *Am J Otolaryngol, 36*(3), 411-414. doi:10.1016/j.amjoto.2015.01.017

Improving Management of Chronic Heart Failure

Mussi, C. M., Ruschel, K., de Souza, E. N., et al. (2013). Home visit improves knowledge, self-care and adhesion in heart failure: Randomized Clinical Trial HELEN-I. *Rev Lat Am Enfermagem, 21 Spec No*, 20-28.

Neumann, T., Biermann, J., Erbel, R., et al. (2009). Heart failure: the commonest reason for hospital admission in Germany: medical and economic perspectives. *Dtsch Arztebl Int, 106*(16), 269-275. doi:10.3238/arztebl.2009.0269

Norton, C., Georgiopoulou, V. V., Kalogeropoulos, A. P., & Butler, J. (2011). Epidemiology and cost of advanced heart failure. *Prog Cardiovasc Dis, 54*(2), 78-85. doi:10.1016/j.pcad.2011.04.002

Packer, M., Bristow, M. R., Cohn, J. N., et al. (1996). The effect of carvedilol on morbidity and mortality in patients with chronic heart failure. U.S. Carvedilol Heart Failure Study Group. *N Engl J Med, 334*(21), 1349-1355. doi:10.1056/NEJM199605233342101

Pfuntner, A., Wier, L. M., & Stocks, C. (2006). Most Frequent Conditions in U.S. Hospitals, 2011: Statistical Brief #162 *Healthcare Cost and Utilization Project (HCUP) Statistical Briefs*. Rockville (MD).

Ponikowski, P., Anker, S. D., AlHabib, K. F., et al. (2014). Heart failure: preventing disease and death worldwide. *ESC Heart Fail, 1*(1), 4-25. doi:10.1002/ehf2.12005

Punchik, B., Komarov, R., Gavrikov, D., et al. (2017). Can home care for homebound patients with chronic heart failure reduce hospitalizations and costs? *PLoS One, 12*(7), e0182148. doi:10.1371/journal.pone.0182148

Reilly, C. M., Butler, J., Culler, S. D., et al. (2015). An economic evaluation of a self-care intervention in persons with heart failure and diabetes. *J Card Fail, 21*(9), 730-737. doi:10.1016/j.cardfail.2015.06.382

Rodriguez-Gazquez Mde, L., Arredondo-Holguin, E., & Herrera-Cortes, R. (2012). Effectiveness of an educational program in nursing in the self-care of patients with heart failure: randomized controlled trial. *Rev Lat Am Enfermagem, 20*(2), 296-306.

Roger, V. L., Go, A. S., Lloyd-Jones, D. M., et al. (2012). Heart disease and stroke statistics--2012 update: a report from the American Heart Association. *Circulation, 125*(1), e2-e220. doi:10.1161/CIR.0b013e31823ac046

Sidhu, R. S., Youngson, E., & McAlister, F. A. (2014). Physician continuity improves outcomes for heart failure patients treated and released from the emergency department. *JACC Heart Fail, 2*(4), 368-376. doi:10.1016/j.jchf.2014.03.006

Stewart, S., Carrington, M. J., Marwick, T. H., et al. (2012). Impact of home versus clinic-based management of chronic heart failure: the WHICH? (Which Heart Failure Intervention Is Most Cost-Effective & Consumer Friendly in Reducing Hospital Care) multicenter, randomized trial. *J Am Coll Cardiol, 60*(14), 1239-1248. doi:10.1016/j.jacc.2012.06.025

Vaduganathan, M., Bonow, R. O., & Gheorghiade, M. (2013). Thirty-day readmissions: the clock is ticking. *JAMA, 309*(4), 345-346. doi:10.1001/jama.2012.205110

van Walraven, C., Jennings, A., & Forster, A. J. (2012). A meta-analysis of hospital 30-day avoidable readmission rates. *J Eval Clin Pract, 18*(6), 1211-1218. doi:10.1111/j.1365-2753.2011.01773.x

Yancy, C. W., Jessup, M., Bozkurt, B., et al. (2013). 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol, 62*(16), e147-239. doi:10.1016/j.jacc.2013.05.019

Ziaeian, B., & Fonarow, G. C. (2016). The Prevention of Hospital Readmissions in Heart Failure. *Prog Cardiovasc Dis, 58*(4), 379-385. doi:10.1016/j.pcad.2015.09.004