



NELL HODGSON
WOODRUFF
SCHOOL OF
NURSING

March 1, 2012

Dr. Fred Sanfilippo
Re: Seed Grant in Health Care Innovation

Dear Dr. Sanfillippo,

We are pleased to submit an application for the HIP Seed Grant in the Preliminary Study Category for: "A Preliminary Test of iHealthHome for Improving outcomes in Persons with Heart Failure and Diabetes." The iHealthHome system is a comprehensive in-home monitoring, communication, and collaboration care system designed and developed for older adults living alone. We propose to adapt this system to support persons in self-managing heart failure and concomitant diabetes. Approximately 30-47% of persons with heart failure have concomitant diabetes mellitus, and this population is at high risk for multiple hospitalizations and poor health outcomes. This small pilot study will bring together the expertise of nursing, cardiology and health engineering to modify the existing iHealthHome system content and pilot the study with 10 patients to determine its effects on knowledge and confidence for self care, as well as performance of self care behaviors that would prevent re-hospitalization. The data from this study would be used to support a larger trial testing the system for improved health outcomes and health care utilization.

The multi-disciplinary investigative team includes:

Dr. Sandra Dunbar, Dr. Carolyn Reilly, Dr. Melinda Higgins, and Dr. Rebecca Gary – Emory School of Nursing
Dr. Javed Butler – Emory School of Medicine
Brian Jones - Director, Aware Home, and Senior Research Engineer Jiten Chhabra, MD, Research Faculty and Scientist, Georgia Technological Institute

This team has been examining approaches that blend the clinical and research expertise from Emory with the technology and human-computer interface experts from Georgia Tech. The study is proposed with in-kind support and collaboration with Ho'okele Health Navigators.

The total budget that will be requested will be \$25,000. Thank you for your consideration of this application.

Sincerely,

Sandra B. Dunbar, RN, DSN, FAAN, FAHA
Professor, On behalf of the investigators

A Preliminary Test of iHealthHome for Improving Outcomes in Heart Failure Patients with Diabetes

A. Introduction and Specific Aims

This proposal is in response to the *Health Care Innovation Seed Grant* program and will focus on the design and test of an approach to assisting persons with heart failure (HF) and concomitant diabetes mellitus (DM) to improve their home based self-care in an effort to ultimately reduce health care utilization and improve quality of care. The project will focus on several identified priorities within the *Call for Proposals* including 1) the discovery and testing of interventions that will improve health outcomes, costs, cost-effectiveness, 2) the development of a multi-disciplinary team across Emory University School of Nursing and Georgia Tech.

HF is a serious epidemic affecting over 5.7 million persons in the United States,¹ with up to 2.6 million also diagnosed with DM.^{2,3} As the most common cause of hospitalization in elders,⁴ HF accounts for 6.5 million annual hospital days and over 12 million office visits,¹ with excess rehospitalizations reported as high as 47% by 90 days^{5,6} and 54% within 6 months,⁷ of which 40-60% are considered preventable by greater provider attention to standards of care and better patient self-care.⁸⁻¹⁰ Medicare claims data reflect increasing incidence and prevalence of DM,¹¹ and the prevalence of DM may be rising faster in HF patients than in the general population in that approximately 30%-47% of HF patients also have DM.^{12,13,2,3} There is 40% to 80% excess risk of mortality among HF patients with DM, and a 1.6 fold increase in relative risk for hospitalization over those without DM due to escalating symptoms of HF and comorbidity burden.^{6,14-19} Patients with concomitant HF and DM represent a growing population with poor quality of life and complex self-care.

Self-care behaviors for HF patients include reducing dietary sodium diet, taking HF medications, performing and interpreting daily weights, engaging in physical activity, and monitoring symptoms of dyspnea, fatigue and edema.²⁰ DM patients are taught to manage a diabetic diet, take DM medications, monitor blood glucose, engage in physical activity, and monitor symptoms of hypoglycemia and foot problems.²¹ For both conditions, self-care is hard and fraught with problems of non-adherence and inadequate decision-making.²²⁻²⁵ HF patients with the comorbidity of DM are at greatest risk of being readmitted due to fluid overload and inadequate glycemic control which are preventable with better self monitoring, self-care, and problem-solving. HF may actually lead to less DM self-care prioritization and ability.^{21,26} Tested approaches to prepare and support HF-DM patients for comorbidity self-management are nonexistent but essential to improve patient self-care and ultimately reduce health care resource utilization and total direct medical costs.

To address this problem, we propose to adapt the iHealthHome Navigator system for HF-DM patients. The iHealthHome system is a comprehensive in-home monitoring (blood pressure, blood glucose, weight), communication (email, skype, internet) and collaborative care (provider access to data, patient education, decision support) system designed for older adults living alone. The system goes beyond the traditional telemonitoring approach in that it includes the benefits of the system mentioned above, has capability to tailor modules for education, and to provide feedback to the participant about their self-monitored data. We will add specific content related to self-managing HF and DM together, a unique approach, and provide for self-care promotion through feedback and interpretation of self-monitored BP, weight, and glucose levels. We will be developing communication and motivating messages and technical approaches to reinforce and enhance self care behavior based on monitored data through the innovative communication features.

Therefore, the purpose of this project is to adapt and pilot test the iHealthHome system in persons with HF and concomitant DM. The specific aims are: 1) to develop an integrated self-care intervention for HF patients with DM by adapting the iHealthHome system for comprehensive in-home self-monitoring, communication, and reinforcing education. 2) to conduct a small pilot test of the system for its effects on patient outcomes of HF and DM knowledge, self-efficacy, and self-care behaviors, and trend in monitored data of BP, weight, and glucose, 3) to assess participant perceptions of satisfaction, ease of use and acceptability of the iHealthHome system. These data will be used to assess effect sizes and to inform a larger study and clinical effectiveness trial, testing the system against other approaches and to determine the effects on other health outcomes, such as rehospitalization and cost.

B. Methods and Data Sources

This study represents the next logical step in a program of research designed to improve outcomes for patients with HF through educational and self-management approaches. The PI currently is funded from NIN to test an integrated face to face educational and counseling intervention with persons with HF-DM to determine its effects on patient outcomes, quality of life and costs. The multidisciplinary team representing nursing, cardiology expertise from Emory and computer engineering and design from Georgia Tech will adapt the patient education materials developed for this NIH funded project into a computerized version and incorporate it into the overall iHealthHome system. The new intervention to be developed and tested will be a synthesis of the integrated self-care program and telemonitoring/communication enhancement. The project is the first collaboration among the investigators from Emory and Georgia Tech, who have been meeting together for several months to examine technological approaches to improving patient outcomes. By using patient

education and self-management theory to create improved knowledge, self-efficacy and performance of desired behaviors, HF-DM patients will develop and strengthen skills to self monitor and interpret HF & DM symptoms as well as make choices that lead to appropriate dietary modification, medication taking, and physical activity. The study will go beyond usual telehealth approaches which address only one chronic illness and only one component in HF self-management. We will test a clinically feasible strategy that will enhance the ability to translate the intervention to practice in the future. If the comorbidity intervention is successful, the model may eventually be adapted and tested for its effects in other HF comorbidity groups requiring complex self-care, such as those with HF and chronic obstructive pulmonary disease.

Design: The first phase of the project will address aim I and will adapt the iHealthHome Navigator system using theoretically based approaches for motivating and communicating self management education and support for participants. Various systems using telemonitoring for chronic heart failure management have been tested with inconsistent results, and the primary reasons for this variation are diverse intervention and study designs, heterogeneous HF populations, and a focus on data gathering and tracking versus behavior change.^{27 28} Additional issues with prior studies of telemonitoring are unresolved problems of using complex systems with elders not accustomed to technology in their home, or use of mobile technology too difficult to see and navigate.²⁹ The unique aspects of the iHealthHome should help overcome some of these past barriers, due to the ability to personalize advanced communication in addition to providing a flexible monitoring system, which allows discrete tracking of daily activities in the home and seamless electronic communication among members of a caregiving team. iHealthHome provides a variety of useful features including:

- A touchscreen all-in-one with the iHealthHome user interface supports ease of use, designed with older adults in mind, such as larger on-screen fonts and buttons.
- The Wellness Monitoring feature allows both the participant and provider to review and track blood pressure, weight, and glucose readings. This component will be adapted such that the information provided to both participants and providers will be graphed to help visualize trends.
- Communication system supports emails between the provider and participant, and allows messages and alerts to be displayed. The iHealthHome will be programmed to provide tailored alerts for appointments, and important reminders about self care monitoring. Alerts and Notifications allow caregivers the ability to be informed quickly of unusual changes in routines. Some situations which could trigger alerts might be:
 - When either an excessive amount, or a lack of motion was detected in a specific room in the home, or activity during sleep hours that may be indicative of worsening conditions.
 - If blood pressure, weight or blood glucose measurements have not been taken according to designated schedule
 - A significant increase or decrease in blood pressure, weight, or blood glucose is detected
 - auditory voice message to remind a participant to take medications at a certain time each day.
- The Pictures module allows for sharing of photos and candid or planned photo sessions with the provider. This would allow, for example, a participant to show the provider an image to evaluate the status of ankle edema or new diabetic foot problem such that treatment could be implemented early.
- The Calendar at a glance displays events such as doctor appointments, activities, birthdays, and is tailored to for the individual.
- Websites: The internet is easily accessed to display specific information on HF and DM self-management. Through the Websites feature of the iHealthHome system, we will develop constrained web pages on integrated HF-DM diet and meal plans, medication information, symptom monitoring, interpretation and management, daily physical activity guidelines and exercises, and when to call the provider. Bookmarks will be integrated into the button options of the system to make it easy to access specific sites.

The iHealthHome also has games and brain exercises which can be activated or not. We will not be using these modules in this study, but acknowledge their usefulness for future projects.

As part of the human-centered design process, we will conduct user experience evaluations using low fidelity paper prototypes with potential users of the system to determine how the new information will be presented in the final design. For this exercise members of the design team will ask potential participants to perform a list of tasks related to information retrieval on the various paper prototypes and measure their performance on design heuristics like recoverability, consistency and task conformance. Once the iHealth Home Navigator system has then been adapted with all HF-DM content, and sensors for this project integrated, we will invite a few potential participants to review the prototype to determine their perceptions of here and when the new information (graphs, interventions) should be presented in the new design.

The second phase of the project will include an initial testing of the system with at least 2 HF-DM patients recruited from the Emory Center for Heart Failure Therapy with assessment of the ease of use and a chance to modify components. A second test of the refined system will take place with an additional 6 HF-DM patients. The data from these participants will be used to address Aim II and III. This is a single group, pre and

post test design. Data will be collected prior to installation of the iHealthHome system in the participant's homes and again at 2 months.

Sample: Approximately 6-8 persons with HF and DM will be enrolled. The inclusion criteria are ages 50-80 years, diagnosis of HF with concomitant DM type II, residing at home, NYHA Class II-III, on optimal HF medications, including ACE-Inhibitors or ARBs, beta blocking agents, and diuretics (if indicated by patient fluid status), ambulatory, able to read and write English, acceptable cognitive screening test, internet access in home. Exclusion criteria are: active foot ulcers, presence of hemodynamically significant angina pectoris, renal failure, planned cardiac surgery, impaired cognition, psychiatric diagnosis; uncorrected visual or hearing problem; moderately severe depressive symptoms (> 17 on the PHQ) and evaluation for transplant or ventricular assist device, lack of telephone access. The inclusion/exclusion criteria were selected to eliminate conditions that would confound the ability to participate or confound the dependent variables. By requiring participants to be on certain HF medications, we will reduce variable effects of medications and will examine the intervention effect in the context of optimal medical therapy. The rationale for depression screening is that depressive symptoms may reduce ability to perform self-care in HF and DM. By including NYHA Class II & III and adequate renal function, we will reduce variability in the outcome measures and target HF-DM patients most likely to benefit from improved self-management as well as those with less severity of illness in an effort to establish effective HF-DM self-management behaviors early in the disease trajectory.

Variables and Measures: Variables will be measured by valid and reliable indicators of HF and DM knowledge and self efficacy, and patient self-care behaviors as noted in Aim II. We have selected instruments for their brevity. Table 1 depicts the variables, measure and measurement times.

Table 1. Variables, instruments, and time frame

Variable	Measure/Instrument	# of items	Time of Evaluation
Screening questionnaires			Enrollment
Cognition	Blessed cognitive screen	6 (2 minutes)	
Depressive Symptoms	PHQ 9	9 (4-5 minutes)	
Demographics & Clinical information	Age, gender, education, marital status, Charlson comorbidity Index (CMI), LVEF, NYHA class, length of time with HF & etiology, length of time with DM, presence of DM complications, Medications	Medical Chart review & questionnaire and interview	Baseline Review at 2 months for any changes
Self-care Processes			Baseline and 2 months
Knowledge	HF: knowledge (AHFKTv2) DM: Michigan Diabetes Knowledge Test	30 23	
Self-efficacy	HF: SCHFI – (self confidence subscale) DM: Perceived Diabetes SM Scale	4 8	Baseline and 2 months
Self-management Behaviors	HF : SCHFI (maintenance, management subscales) DM: Summary of Diabetes Self Care Activities Dietary composition (24 hour dietary recall) Physical Activity: Physical Activity Counts monitored from iHealthHome Navigator	11 11 (10-15 min)	Baseline and 2 months
Outcomes	Monitored BP, weight and glucose trends Health resource use		

Instruments:

1. **Demographic/clinical and Screening:** age, gender, marital status, education, ethnicity, time with and type of HF, LVEF, NYHA Class time with DM, and medications will be obtained from the medical record. The short **BLESSED cognitive screening tool (BOMC)** will be used to exclude those with scores ≥ 11 indicating cognitive impairment that would interfere with participation.³⁰ The BOMC has excellent validity as a screening instrument,³¹ correlates highly with clinicians' ratings of dementia severity ($r = .89$).^{32 30 33} The Charlson comorbidity index (CMI) was developed to quantify risk of death from comorbid diseases.³⁴ These variables will be used to fully describe the sample. The PHQ-9 is a 9-item depression scale and will be used to exclude those with a score in the moderately severe range.³⁵ The internal reliability of the PHQ-9 is excellent with a Cronbach's alpha of .89, strong test retest reliability and demonstrated construct validity.³⁵

2. **Self-care Processes:**

2a. **HF and DM Knowledge:** The Atlanta *HF Knowledge Test.v2 (AHFKTv2)*³⁶ is a 30- item knowledge test which will be used to test knowledge of HF dietary self-care and medication taking behaviors. Developed by our team, the knowledge test has true-false and multiple choice items at a 4th grade reading level. Content validity ratings on relevance and clarity ranged from .55 to 1.0 with 81% of the items rated .88-1.0. Cronbach's alpha was 0.85. Construct validity testing revealed a small but significant correlation between higher patient knowledge on sodium restriction questions and lower ingested sodium, $r = -.17, p = .05$, and between patient knowledge and number of days medications were taken correctly.³⁶ *DM knowledge* will be tested by the Michigan Diabetes Knowledge Test (MDKT),³⁷ which has two components, a 14-item general diabetes knowledge test and a 9-item insulin use subscale. The test is considered to have internal consistency reliability

(Cronbach's alpha .70)³⁷ The MDKT examines areas of diet, self-care, symptoms, and symptom management related to DM. On both knowledge instruments, the percentage of items answered correctly will be calculated.

2b. Self-efficacy refers to the confidence in ability to perform expected behaviors and is behavior specific. The Self-care in Heart Failure Index (SCHFI) is a self-report measure comprised of 15 questions rated on a 4 point scale and divided into three subscales: self-care maintenance, self-care management, and self-care confidence.³⁸ The self-care confidence subscale of the SCHFI will be used to assess self-efficacy in HF and is comprised of 4 items reflecting confidence in recognizing symptoms and taking HF self-care actions. Internal reliability consistency is acceptable for the subscale (alpha= .82). The Perceived Diabetes Self-Management Scale (PDSMS) is an eight item instrument designed to test diabetes self-efficacy. The total score can range from 8 to 40, and Cronbach's alpha is reported at .83.³⁹

2c. Self-Care Behaviors: The SCHFI is a 15 item instrument measuring self-care in persons with HF,³⁸ and reliability for the entire instrument has been reported as adequate (alpha = .76). Two of the subscales (self-care maintenance (alpha = .60), self-care management (alpha= .70) will be used to assess self-care in HF. Behaviors measured by this instrument include weighing, diet, PA, symptoms, medications, contacting the provider. The Summary of Diabetes Self-Care Activities (SDSCA) scale has a core set of 11 items used to assess 5 diabetes self-management behaviors of diet, exercise, smoking, foot checks, and blood glucose testing. Studies have demonstrated adequate internal (.70) and retest reliability, with sensitivity to change.⁴⁰

We will take a closer look at self care behaviors of diet and PA given the emphasis of the intervention.

24 hour diet recall: The trained RN will utilize the Nutrition Data System for Research (NDS-R), a Windows based dietary analysis program designed for collecting and analyzing 24-hour dietary recalls. Study participants will be interviewed at the home visit and again at the 2 month evaluation, and will include a detailed history of the participant's dietary intake over the previous 24 hours, including foods, liquids, and nutritional supplements. Portion size estimates will be aided by reference to the pictures depicting different portion sizes for various foods and beverages provided in the study materials at the time of hospital discharge. Participants will be instructed to use the system to log an image of their meal plates using the iHealthHome system. The obtained dietary data is then analyzed using the NDS-R to obtain dietary intake of total calories, fat, saturated fat, sodium, total sugars, and carbohydrates. The 24 hour recall method is a valid and reliable method to capture dietary intake, has less burden than 3 or 4 day food records, and greater sensitivity over food frequency questionnaires for assessing short term changes.⁴¹ Physical Activity The iHealthHome system has a series of activity monitors that are installed throughout the home. The total activity count can be identified or the activity in a specific room, such as a bedroom, will be chosen. Clearly this is limited by oversensing due to others in the home, or oversensing due to activity out of the home. We will examine activity counts during night which could indicate potential HF problems. We will ask participants to keep logs on the presence of others, and to document physical activity outside the home.

Outcomes: The blood glucose, blood pressure, symptom and weight data monitored through the study will be downloaded and analyzed for trends at the end of the study. A log of rehospitalizations, provider and ED visits, and calls to providers will be kept.

Process Measures: A brief evaluation tool to determine participant's perceived benefit, usefulness and ease of use, and satisfaction with the intervention will be collected at the end of the study. Time logged into the specific components will be tracked. Participant suggestions for improvements will be obtained.

The protocol for recruitment, screening, and enrollment, intervention, and data collection is in Appendix A.

Data Management and Analysis: The anticipated results of the study are the developed of a unique approach to patient self care support and care coordination, and improved self care knowledge, confidence, performance of behaviors and improved trends in self monitored data of BP, weight and glucose. Data management will be overseen by the study biostatistician who will design and conduct the statistical analysis, participate in designing research forms and data entry programs, and collaboratively work with the other investigators in analysis and interpretation. All demographic and clinical characteristics will be described using descriptive statistics. Scores on instruments (AHFKT, MDKT, SCHFI, PDSMS, SDSMA) will be examined for change from pre to post test values using statistics appropriate for paired data, the sample size, and for the distribution obtained. Change in nutrients of interest from the 24 hour diet recall and activity counts will be analyzed. Effect size for each variable will be calculated for use in future studies. The blood glucose, blood pressure, symptom and weight data monitored through the study will be downloaded and analyzed for trends at the end of the study. These data logs will be reviewed for completeness, % of days recorded, and trends associated with effective change. Participant ratings of satisfaction, ease of use, and acceptability will be summarized. Health resource use over the time of the study will be described. We acknowledge limitations of the small sample size and lack of a control group, however, the emphasis is on the development and pilot of a unique approach and the preliminary data is essential for the future larger test of this potentially cost effective approach to HF-DM management.