IRB PROTOCOL: Telehealth Self-Management Program in Older Adults Living with Heart Failure in Communities with Health Disparities

SPONSOR: Patient Centered Outcomes Research Institute (PCORI)

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INTRODUCTION/BACKGROUND MATERIAL/PRELIMINARY STUDIES AND SIGNIFICANCE

Disparities in cardiovascular disease (CVD) have received particular focus, as CVD is a major contributor to differences in morbidity and mortality between blacks and whites.[1-5] Blacks are more likely than whites to develop CVD and die at earlier ages from heart failure, stroke, and myocardial infarction.[6,7] The incidence of chronic heart failure (CHF) is equally frequent in men and women.[8] The relative incidence of CHF is 50% higher in African Americans compared to the general population. Moreover, the disease occurs at an earlier age, resulting in more advanced disease severity.[9] Likewise, Hispanics with CHF are younger and die earlier than non Hispanic whites. The reasons for this greater disease burden of CHF in African Americans and Hispanics are complex, resulting from the interaction of factors such as hypertension, diabetes, obesity, reduced health care access, socioeconomics and cultural factors.[6,10,11] Given the larger burden of CHF in these populations and the unfavorable disease outcomes, a tailored and more focused management of this clinical condition is warranted.

CHF is the most frequent diagnosis in hospitalized patients over 65, and is a leading cause of disability and death.[12,13] CHF is a progressive chronic disease characterized by a variety of CVD problems leading to cardiac dysfunction and eventually to the typical CHF symptoms such as dyspnea, fatigue, and congestion.[9] CHF is characterized by recurrent periods of clinical exacerbation that often lead to frequent physician office visits, high rates of emergency room (ER) and inpatient hospital utilization. Unfortunately, most community-dwelling patients living with heart failure receive exacerbation-focused care without a comprehensive chronic management program. At present, neither patients nor their caregivers have the knowledge and the skills to participate in managing this disease. Usual care results in repetitive, inefficient and costly cycles of hospitalization, rehabilitation and home care after exacerbation followed by no monitoring, with the exception of the occasional physician office visit. This lack of management leads to poor health outcomes, including decreased quality of life, decreased functional status and increased health care costs.

The use of telehealth is a promising approach to optimizing outcomes in the treatment of CHF for patients living in the community. As exacerbations of CHF are common in the disease progression, the use of telehealth to monitor physiologic indicators, such as weight, heart rate, lung sounds, and blood pressure enables improved management through timely treatment adjustments. Without leaving their homes, patients can upload vital signs and be monitored by clinicians through telehealth visits using voice and video equipment combined with peripheral medical technology. Telehealth self management (TSM) can provide the patient with self-management tools to facilitate follow-up care.[14] Interactive health information technology not only provides health tools and health information that is patient centered but also engages patients and promotes their active participation in improving their health and their quality of life (QoL).[1516,17]

Although many telehealth trials in community-dwelling seniors have been published, there is limited literature on the use of telehealth in ***underserved populations***. The few telehealth studies conducted in disparity populations have focused primarily on diabetes and blood pressure management. Given the great discrepancy in prevalence rates of CVD disease and its manifestations between whites and ethnic minorities, coupled with the disparities in access to innovative and effective treatments between upper/middle and lower socioeconomic classes, it

is imperative that researchers and clinicians bring effective interventions to these at-risk populations.

The previous work of our research team includes a two-year randomized trial, a two-year matched control study, and a three-year randomized trial (currently underway). We have shown that TSM can create cost savings and shorter lengths of stay for those hospitalized. The present study proposes to test this technology with an underserved population to determine whether our previous results are generalizable.[26]

OBJECTIVE(S)/SPECIFIC AIMS AND HYPOTHESES

Research Question: *Can we narrow health disparities through TSM by providing the proposed disparity population with skills to monitor their health status daily and weekly access to a health practitioner through a scheduled telehealth video visit?* We **hypothesize** that TSM patients will have significantly better outcomes: greater QoL and lower hospital utilization over 3 months than those receiving usual care.

In this study, we will apply appropriate and rigorous research methods to: *a*) assess patient acceptance and usability using a mixed methods approach*;* and *b) directly compare TSM to standard of care* in a health disparity population.

Aim 1: we will conduct a process evaluation to assess telehealth acceptance and usability among low-income, largely minority seniors living with CHF NYHA class 1-3.

We will use a mixed methods approach to look at indicators of usability, including qualitative measures, such as: 1) focus group feedback from key community stakeholders, including patients and caregivers, and quantitative measures, such as 1) rate of study participation acceptance; 2) self-monitoring behavior (as measured by vital sign uploads); 3) visit participation; 4) patient satisfaction; and 5) ease of use of measures.

Aim 2:, we will conduct the first randomized controlled trial (RCT) to telemonitor minority community-dwelling patients with CHF (NYHA class1-3) for 3 months after hospital discharge for CHF. We will compare hospital and emergency room utilization, as well as QoL, between TSM and standard of care groups.

According to the NYHA classification system, patients experience increased limitations in physical activity, such as fatigue, palpitation and angina pain, from mild in class 1 to extreme in class 4. Patients in class 4 experience these symptoms even at rest, and are usually bed-bound. We specifically excluded seniors with heart failure NYHA class 4 because they are primarily bed-bound and highly unlikely to be able to participate in the tasks required of the intervention.

Specifically, after hospitalization for a CHF exacerbation at NUMC, patients will be approached by the heart failure clinic nurse to assess interest in participation. The study will be described in detail, and patients will be assured of confidentiality. Once patients give permission, the clinic nurse will personally introduce the patient to the research nurse, and reiterate their willingness to participate, the formal consent process will occur. Patients will be randomized once they have given consent to participate in the study.

EXPERIMENTAL DESIGN

Aim 1: we will conduct a process evaluation to assess telehealth acceptance and usability among low-income, largely minority seniors living with CHF NYHA class 1-3.

We will assess usability of an existing Heart Failure telehealth intervention and will adapt the intervention to facilitate acceptability and feasibility in a population of low-income ethnic minority patients. Usability will be assessed throughout the study period through the examination of usability indicators presented temporally below.

1a. **Pre-study usability (stakeholder perspective):** Qualitative methodology (i.e., focus groups) will be used to gather information regarding intervention adaptation to ensure patient acceptability and feasibility from the community advisory board (CAB) which will include patients and key stakeholders. The CAB will consist of individual Heart Failure patients and caregivers in the community and individuals within the community with whom the PI has already forged relationships in addition to members of the NUMC advisory board. This CAB is demographically and geographically representative of the patient population at NUMC. CAB members will be compensated $50 for attendance at each meeting. Two focus group discussions will be conducted with CAB members in a confidential meeting room at NUMC. Each one will last approximately 2 hours and will be audiotaped using two digital voice recorders (one for backup in case of technical failure) and professionally transcribed. CAB members will be presented with the intervention (in English and Spanish) including its core components (non-adjustable components) as well as its key characteristics that can potentially be adjusted to formulate the initial implementation of the intervention. The second focus group will occur immediately after adaptation (but prior to intervention implementation) to ensure that we have effectively incorporated all of the CAB feedback. We have already anticipated and addressed some adaptation issues (e.g., having the intervention technology available in Spanish and having a study nurse who is fluent in Spanish; using air cards, as some patients are not going to have landlines or broadband). The focus group discussion will be facilitated by Drs. Taylor and Schwartz and the discussion will be guided by predetermined topics outlined in the attached interview guide (see Appendix 1). To ensure that the patient representatives in the CAB will have ample space and time to express their ideas and thoughts, Drs. Schwartz and Taylor will prioritize their contributions above the medical and professional stakeholders. Structural coding will be used to mark responses to topical questions in the interview guide.[20] Following a review of the a priori topics, Drs. Schwartz and Taylor will use grounded theory to develop a codebook to categorize the data and identify salient themes and relationships.[21,22] Using thematic analysis, each transcript will then be independently coded by Drs. Schwartz and Taylor using NVivo [23] software. The main themes that emerge will specify any necessary adaptation that the CAB believes should occur.

1b. Patient Usability (patient perspective): We will also conduct a focus group with the initial 10 patients enrolled in the intervention arm of the study to obtain user feedback regarding any barriers to implementation or usability suggestions to further adapt the intervention if necessary before additional participants are enrolled. The qualitative methods detailed above will be employed. The patient focus group will take approximately two hours and will be conducted in a confidential conference room at NUMC. Patient participants will be compensated $50 for their participation. The discussion guide for the patient focus group will be developed by the Drs. Schwartz and Taylor with input from the CAB (see Appendix 2). Discussion topics include (but are not limited to) the following: 1) patients' perceptions of the ease of the study implementation (using the equipment, uploading) 2) patients' perceptions of usefulness of the intervention; 3)

patients' input on barriers/challenges to intervention implementation; and 4) suggestions for improvements and/or adjustments that should be made. Data will be coded and analyzed using NVivo (see above) to identify the barriers and challenges that need to be addressed as study implementation continues in order to ensure a high level of usability.

Patient Utilization: This phase of intervention development will also involve an ongoing process evaluation of usability using quantitative methodology. Again, this is so that adjustments can be made, as necessary, as the TSM intervention is implemented.

We will operationalize usability using the following measures:

1) Rate of acceptability
2) Rate of installation acceptance
3) Upload compliance
4) Total number of visits
5) Patient satisfaction

Aim 2: we propose to conduct the first randomized controlled trial to telemonitor minority community-dwelling patients with CHF (NYHA class1-3) for 3 months after hospital discharge or CHF. We will compare hospital and emergency room utilization, as well as QoL, between TSM and standard of care groups.

This is a prospective randomized controlled trial of 104 community-dwelling patients from disparity communities living with CHF 18 years and older.

In this study, patients will be randomized either to TSM or to standard of care once they have given consent to participate to *directly compare TSM to standard of care* in a health disparity population.

Table 1. Proposed Intervention: TSM and Standard of Care (SOC)

Meaures	TSM	SOC
Quality of Life Living with HF Questionnaire (Months 1 and 3)	x	x
NYHA Functional Score (Months 1 and 3)	x	x
Telemedicine Satisfaction and Usefulness Questionnaire (Month 3)	x	
PHQ4 to assess symptoms of depression and generalized anxiety disorder (Month 1)	x	x
DAILY ELECTRONIC TRANSMISSION OF VITAL SIGNS		
Blood Pressure	x	
Pulse	x	
Oxygen Saturation	x	
Weight	x	
WEEKLY VISIT	**Video**	**Phone**
Blood Pressure	x	
Pulse	x	
Oxygen Saturation	x	
Weight	x	
ER Utilization (Primary Outcome Variable)	x	x
Hospitalizations (Primary Outcome Variable)	x	x
Receipt of IV Diuretic	x	
Adherence with Diet Recommendations	x	
Dyspnea	x	
Fatigue	x	
Edema	x	
Death	x	x

Patients with CHF will be subjected to either TSM or standard of care as follow:

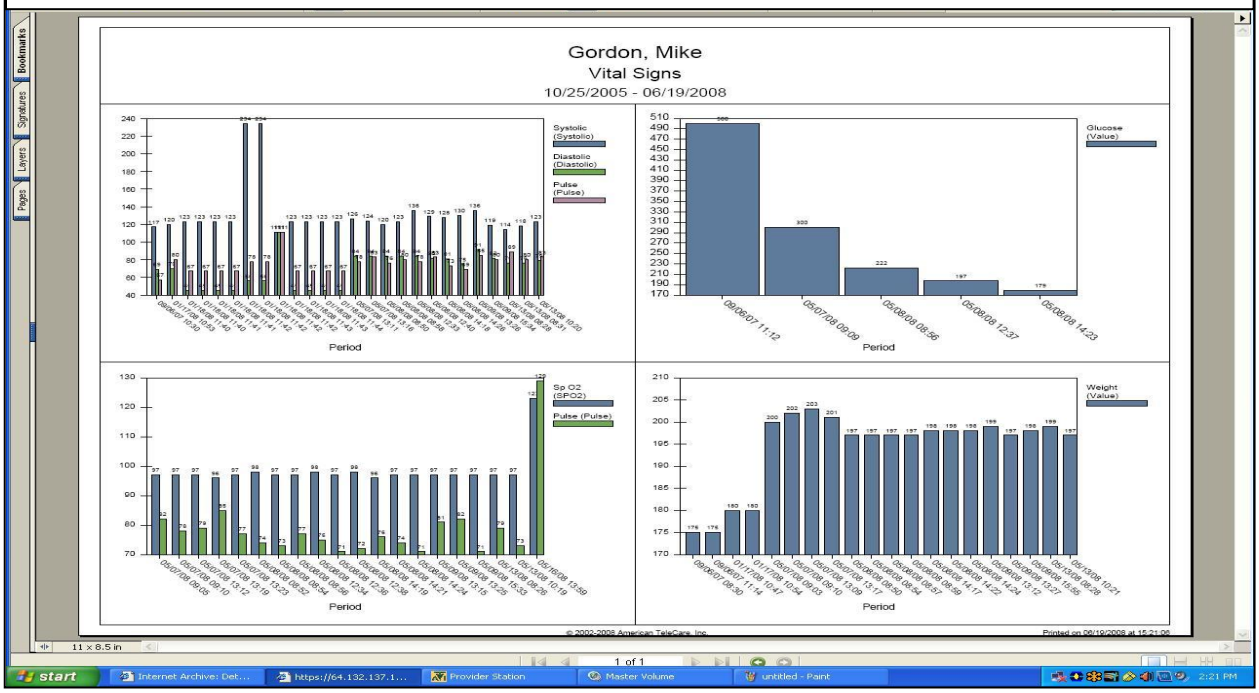
TSM Intervention. TSM is defined as a weekly visit and self-monitoring of daily vital signs utilizing a Subject Monitor which connects from the subject's residence, via a standard telephone line to the provider station (American TeleCare® Provider Station available in both English and Spanish language).

TSM has two components:

1) **a daily vital signs self-monitoring component (client-side operation)**, which requires the subject to monitor and transmit standard key indicators of possible condition exacerbation to the server including blood pressure, oxygen saturation, weight, and pulse/heart rate, and
2) **a weekly telehealth visit**, wherein patients are instructed to attend a regularly scheduled video visit with the practitioner (real time), and queried regarding their behavior and condition during that week.

TSM Intervention Component 1: daily vital signs. Daily Vital Signs (Entered, Transmitted and Reviewed Daily). Patients will be trained by the practitioner how to utilize the peripherals that attach to the equipment (blood pressure cuff, pulse oximeter, weight scale and stethoscope) and will be instructed how to enter key indicators into their subject station on a daily basis. During these daily transmissions, which take about 10 minutes, patients will sit in front of the patient station and attach each peripheral so that automatic transmissions of each key indicator will be automatically sent and stored on the server database. Key indicators include: blood pressure, oxygen saturation rate, weight, and pulse/heart rate. The transmittal time is scheduled and a reminder alarm alerts the patient at the patient/practitioner-determined time of day. The patient, hearing the alarm, answers interview questions, and transmits vital signs. Patients will be instructed to call their practitioner if their readings are out of range to discuss next steps. The range is established as per physician guidelines. The telehealth practitioner will review transmitted indicators within 24 hours post-transmission, and within 72 hours on weekends. If values for key indicators are outside the normal range, then the subject/significant other may be: a) reassured that readings are benign in nature; b) instructed to conduct a telehealth visit; c) instructed to call their physician or, for urgent matters, the practitioner may call the physician him/herself. Figure 2 presents typical vital signs feedback (blood pressure, oxygen saturation, pulse, and weight) generated for the patient, allowing them to easily identify out-of-range values. For patients whose primary language is Spanish, the modules will be provided in Spanish.

Figure 1. Daily vital signs generated for the patient.



<u>TSM Intervention Component 2: Telehealth Visit.</u> Once a week, patients will be instructed to connect to the patient station for a weekly scheduled video telehealth (TSM) visit with the telehealth nurse. The video visit allows the subject and the provider to view one another and listen to the patient's heart and lung sounds. During the telehealth video visit, the patient and provider will discuss signs and symptoms of CHF and the practitioner will review the weekly uploads. Table 1 presents the indicators that will be obtained through the weekly visit for TSM and control patients in detail. For example, if the patient reports edema, further questioning will clarify the location and degree of the swelling and a treatment plan will be initiated. The

telehealth nurse will also ask the patient to show the area where edema is occurring on the monitor using the video camera on the telehealth machine. In addition, the provider will initiate a discussion regarding the importance of fluid and sodium management (see Table 2 for patient education management). In addition to these two components, QoL will be assessed at enrollment (immediately post-consent) and three months after enrollment utilizing the Minnesota Living with Heart Failure Questionnaire (QOL). Patients will also be assessed for symptoms of depression and generalized anxiety disorder using the PHQ4 questionnaire[19] (Month 1; see appendix 5).

Standard of care (Control Group). Patients in the control group will receive usual care at NUMC Heart Failure clinic (primary and cardiac care as reimbursed by Medicare or sliding scale/uncompensated care). As noted above, usual care patients will be contacted on a weekly basis in order to maintain comparable frequency of contact. As detailed in Table 1, patients will be queried regarding ER, hospital utilization (primary outcome variables). They will also be assessed, at months 1 and 3, for QoL and for symptoms of depression and generalized anxiety disorder using the PHQ4 questionnaire[19] (Baseline; see appendix 5). Finally, at the end of the study (month 3), they will be asked if their home care agency supplied any type of telehealth intervention using the attached survey (Control group exit survey).

SCHEDULE OF EVENTS: The table below delineates the expected schedule of events. Major milestones include: patient recruitment, CAB meetings, CAB focus groups, patient focus group, and data analysis.

104 Subjects Randomized to TSM (n=52), and Usual Care (n=52) - Following Subjects for 3 Months

	Month 1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	M13	M14	M15	M16	M17	M18	M19	M20	M21	M22	M23	M24	M25	M26	M27	M28	M29	M30	M31	M32	M33
TSM	FIRST CAB FOCUS GROUP	2nd CAB FOCUS GROUP AFTER INTVN	1	1	2	2	2	2	PATIENT FOCUS GROUP	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	3 MONTHS FOLLOW UP			Data analysis
Control			1	1	2	2	2	2		2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	3 MONTHS FOLLOW UP			
Total enrolled			2	2	4	4	4	4		4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	3 MONTHS FOLLOW UP			
	CAB	CAB											CAB												CAB							CAB	

INCLUSION AND EXCLUSION CRITERIA Subject Selection

Inclusion Criteria for CHF Patients and CHF patient focus group: 1) CHF patients about to be discharged from NUMC or within a week from discharge; 2) 18 years and older; 3) NYHA class of 1-3; 4) primary language of Spanish or English; 5) access to a phone (land line or cell); 6) Folstein MMSE score of 21 or higher; 7) anyone who self identifies as Black/Latino/multiracial (must include black or Hispanic). We will also conduct a focus group with the initial 10 patients enrolled in the intervention arm of the study to obtain user feedback regarding any barriers to implementation or usability suggestions to further adapt the intervention if necessary before additional participants are enrolled.

Inclusion criteria for CAB focus groups: The CAB will consist of CHF patients (and caregivers in the community and stakeholders (individuals) within the community with whom the PI has already forged relationships, in addition to members of the NUMC advisory board; Inclusion criteria for patients participating the CAB focus group are: patients with CHF, NYHA class 1-3 and at least 18 years old. No inclusion or exclusion criteria for the other member of the CAB group, such as stakeholders and caregivers.

Exclusion Criteria for CHF patients and patient focus group: 1) seniors with heart failure NYHA class 4 (because they are primarily bed-bound and highly unlikely to be able to participate in the tasks required for the intervention); 2) Anyone under age 18; 3) Anyone with no access to a phone; 4) Anyone with a primary language that is not English or Spanish; 5) Anyone with a Folstein MMSE score under 21 (indicative of cognitive impairment); 6) Anyone who declines consent; 7) Anyone who does not identify as Black/Latino/multiracial; 8) Patients who have chosen a home care agency that provides telehealth monitoring. Therefore, patients will be contacted and enrolled only after they have chosen their home care agency.

No exclusion criteria for members of the CAB group.

RECRUITMENT PROCEDURES

Individuals participating in the focus groups and CAB will consist of patients with CHF, caregivers and patient's stakeholders in the community with whom the PI has already forged relationships in addition to members of the NUMC advisory board. Drs. Schwartz and Taylor will review the consent form with these individuals and consent will be obtained if the subject is willing to be part of the study.

When discharge from NUMC is imminent, Deborah Ahern, NP, the Director of the NUMC Heart Failure Clinic, will review the study with the patients and consent will be obtained if the subject is willing to be part of the study. The study will be described in detail, and patients will be assured of confidentiality. Once patients give permission (in writing) to discuss the study, the clinic nurse will personally introduce the patient to the bi-lingual research nurse (TBA), and reiterate their willingness to participate, the formal consent process will occur. The research nurse will discuss the study with the patient, including a discussion of the overall goals of the study, the study design, the study time frame (3 months), and the randomization procedures. The nurse will also gather basic information regarding inclusion and exclusion criteria (ex., NYHA class). If the patient meets the inclusion criteria, the nurse will read the consent form aloud, in the patient's primary language, which contains information regarding confidentiality of protected health information, the de-identification of data, risks and benefits of study participation and a description of compensation for participation. The nurse will explain that the information collected regarding daily health could be shared with the patient's physician when necessary, but is completely de-identified for research purposes and will not be shared with anyone else at any time. The consent form will also underscore that the patient can withdraw from the study at any time with no consequences. The nurse will also make sure that the patient understands that he/she will be randomized to either the telehealth self management (TSM) intervention or a control group which is standard of care. However, the nurse will explain to the patient that enrollment for the telehealth arm of the study has ended and he/she will be enrolled in the standard of care arm. If the patient agrees to participate, she/he will be asked to sign an informed consent form. The informed consent will comply with all HIPAA and IRB requirements. We will conduct a block randomization technique to ensure equivalency of gender and Heart Class 3 patients across the two groups. Patients will be randomized by the Feinstein

Biostatistics Unit, as utilized in our previous studies. CAB members and patients who participate in the focus groups will be compensated $50. Patients in both arms of the RCT will receive $100 for participation.

INFORMED CONSENT

1) Informed consent for the RCT: Deborah Ahern, NP, Director of the NUMC Heart Failure Center, and Stacy Castillo RN, will review the study with the patient and consent will be obtained if the subject is willing to be part of the study.
2) Informed consent for the CAB focus groups: two members of the study team, Dr. Rebecca Schwartz and Dr. Tonya Taylor will review the study with the participants and consent will be obtained if the participant is willing to be part of the study. If employees are enrolled, they will not be consented by an investigator with supervisory authority over the employee.
3) informed consent for the patient focus groups: two members of the study team, Dr. Rebecca Schwartz and Dr. Tonya Taylor will review the study with the patient and consent will be obtained if the patient is willing to be part of the study

DISCOMFORTS AND RISKS

The risks of participating in the focus groups are minimal in that the topics will involve CAB members' and patients' opinions of the TSM technology as well as study implementation, methodology and dissemination. Efforts will be made by focus group facilitators to ensure that all focus group participants are given time to express any opinions. Focus groups are audio-recorded which may cause slight discomfort among participants, but study team members will reiterate that qualitative study data will be kept confidential and will not impact patient care in any way.

The risks of participating in the TSM RCT portion of the study are no greater that those encountered by community-dwelling patients living with CHF. In fact, the risk of participating in the intervention arm may in fact be *lower*, since there is a nurse in frequent contact with the subject and monitoring vital signs of the subject. For the control group, the risks are identical to those encountered by community-dwelling patients living with CHF. The medications and interventions that a physician would provide to his/her patients are not investigational, and are considered standard of care.

POTENTIAL BENEFITS

Knowledge gained from this program will further our understanding of the use of telehealth self-management programs as effective vehicles in the management of CHF for low-income minority community-dwelling seniors living.

Participants in the study, particularly those receiving TSM, may benefit from both knowledge and comfort gained in learning to self-monitor, as well as improved quality of life (QoL), partially as a result of decreased hospitalizations.
Such outcomes may lead to prioritizing this TSM intervention as a valuable chronic care management tool for community-dwelling seniors: those patients at highest risk for exacerbation. In addition, if TSM proves to be successful, it can set the groundwork for the management of other chronic care conditions (e.g., COPD). Considering that there are few risks to the participants, and information will be kept confidential, the advantages will surely overcome the risks.

DISCONTINUATION OF STUDY/SUBJECT WITHDRAWAL
The patients and CAB members may withdraw from the study at any time after giving consent.

The study may be discontinued at any time. Any actions that may follow such discontinuation of the study will have no impact upon patient care.

ADVERSE EVENTS
Any adverse events, unanticipated problems and protocol deviations will be reported to the IRB as per NSLIJ policy in addition to PCORI, the funding agency. If, during the course of the telehealth monitoring, the telehealth nurse becomes aware that the values for key indicators are outside the normal range, then the subject/significant other may be: a) reassured that readings are benign in nature; b) instructed to conduct a telehealth visit; c) instructed to call their physician or, for urgent matters, the practitioner may call the physician him/herself.

DATA SAFETY MONITORING
Information required from the subjects in this study, whether via subject interview or computerized transmission, is routine data that would normally be collected in a routine office visit with a physician or nurse.

Deborah Ahern, NP, will monitor data and safety, with emphasis on data integrity and patient safety concerns including: review of adverse events, recommendations concerning continuation or conclusion of the study, protection of the confidentiality of the data and the results of monitoring, review of data and study quality. Monitoring will occur once a month.

Any adverse events, unanticipated problems and protocol deviations will be reported to the IRB by the PI as per NSLIJ policy.

De-identified quantitative data will be submitted to the Biostatistics Department and the Department of Population Health for analysis. The data collection tool will be located in the health system server in a password protected file.

CRITERIA FOR EVALUATING RESPONSE/STATISTICAL ANALYSIS

Aim 1: <u>we will conduct a process evaluation to assess telehealth acceptance and usability among low-income, largely minority seniors living with CHF NYHA class 1-3</u>.
This phase of intervention development will involve focus groups with CAB members and patients and it will also involve an ongoing process evaluation of usability using quantitative methodology. Again, this is so that adjustments can be made, as necessary, as the TSM intervention is implemented.

The focus group methodology relies on a grounded theory approach and uses an analytic strategy that has been well documented in the qualitative literature. [21],[22] As described above, our CAB focus groups will be comprised of key stakeholders in the community of the target patient population including patients themselves whose thoughts and opinions will be prioritized during the two CAB focus groups. Further, our patient focus group will consist of patients who

demographically match the patient population and will be key sources of information on the usability of the TSM technology. The representativeness of the focus group participants serves to reduce bias in terms of relevance and acceptability of ethnic minority CHF patients living in low-income communities. The transcription of the qualitative data will be conducted by a transcriber who is unaware of the study aims thereby reducing any researcher bias. The qualitative coding will be initially conducted independently by Drs. Taylor and Schwartz and then through discussion based on grounded theory, the two researchers will work toward consensus. Employment of this strategy also reduces the likelihood of researcher bias.

We will also evaluate usability using the following quantitative measures:

Rate of acceptability. In order to determine the rate of acceptability of TSM in the discharge environment, we will determine, among those who DO NOT consent to be part of the study, the proportion who state that their reason for non-consent is related to the proposed technology vs those who simply do not want to be part of a clinical study that includes randomization and/or longitudinal follow up. This will allow us to compute the "acceptability rate" (as opposed to "acceptance rate" below).

Rate of installation acceptance: Among those who consent and are randomized to the TSM arm, the rate of "acceptance" will be the proportion of patients who then go on to accept installation of the equipment into their homes.

Upload compliance: We are arbitrarily defining three levels of compliance: High, moderate and minimal. "Minimal" compliance is defined as at least one upload per week for 6 out of the 12 weeks. "Moderate" compliance is defined as at least one upload per week for 9 out of the 12 weeks, and "High" compliance is defined as at least three uploads per week for 9 out of the 12 weeks. *A secondary compliance measure will be the number of uploads over* the 90 day period. = *u/d*. (maximum number of possible uploads = *90).* All of these measures will be appropriately prorated for patients who die, or are hospitalized during the study, and are therefore not subject to uploading requirement during those times. With a sample size of 52 patients, the rates of compliance can be estimated to, at worst, +- 13.9%, with a 95% CI.

Total number of visits: We will compute the proportion of 12 scheduled visits that are kept. Therefore, if a patient is being followed for *w* weeks, there should be *w* scheduled visits. If the number scheduled visits that are kept is denoted by *v*, then the proportion of scheduled visits kept = *v/w*. Visit participation rates will be averaged across patients, and the mean rate will be computed, along with 95% confidence intervals. There is a maximum of 12 possible telehealth visits over the 3 month study period.

Patient satisfaction: We will measure patient perceptions of usability using a slightly modified version of the Telemedicine Satisfaction and Usefulness Questionnaire (Appendix 3). This 22-item questionnaire, which utilizes a 5 point Likert scale, will elicit a total sum score of satisfaction/usability that will then be dichotomized into satisfied vs. not satisfied based on previous literature.

Sample size considerations: We will randomize 116 patients as they are discharged from the hospital (58 per arm) in order to yield a maximum of 52 patients in the TSM arm of the study over a two year period.

These scores will be assessed using mean scores, percentages and histograms.[25] For satisfaction rates of 50%, 75% and 90%, with a sample size of 52, the corresponding 95% confidence intervals will have precision of +/- 13.9%, 12.7%, and 8.3%, .

Aim 2: *we will measure inpatient utilization, emergency room utilization and QoL of patients* receiving telehealth technology vs. standard of care patients.

2a. Measures of Inpatient Utilization. Inpatient utilization will be measured in three ways, including: 2a.1) whether an individual subject had at least one inpatient hospitalization over the 3 month period; 2a.2) the number of hospitalizations experienced by an individual subject over the 3 month period; and 2a.3) cumulative length of stay (LOS) (inpatient days) experienced by an individual subject over the 3 month period (i.e., for multiple hospitalizations, the sum of all LOS's will be computed as the cumulative LOS). Cumulative LOS will be analyzed in two ways: intention to treat (ITT) analysis, and for only those hospitalized. The ITT analysis will include all patients, regardless of hospitalization history, to address the bigger public health issue: does TSM have an impact on LOS overall? A secondary analysis will look at LOS only for those who experienced a hospitalization. Finally, after ITT analysis, secondary analyses will include covariate adjustments for possible confounders.

Statistical Methods: Inpatient Utilization. For outcome 2a.1, the proportions of patients in each group who were hospitalized will be compared using the standard Chi-square or Fisher's exact test. Associated 95% confidence intervals for these proportions and their differences will be computed using exact methods. For outcome 2a.2, the number of hospitalizations will be compared using Poisson regression (SAS PROC GENMOD). It is likely that, due to excess zeros (i.e., zero inflation), methods for overdispersed Poisson will be required. Another approach for both outcomes 2a.2 and 2a.3 will be to use Lachenbruch's two stage procedure for zero-inflated data.30 For these primary ITT analyses, no adjustments will be made for any covariates.

Sample size considerations: We expect to enroll 52 patients in the TSM group which will yield the necessary statistical power.

2b. Measures of ER Utilization, defined as: 2b.1) whether or not an individual subject had at least one ER visit over the 3 month period; and 2b.2) the number of ER visits experienced by an individual subject over the 3 month period. Covariate adjustments will be made for potential confounders.

Statistical Methods: ER *Utilization*: The statistical methods for analyzing ER utilization outcomes will be similar to those presented for inpatient utilization. Specifically, for outcome 2b.1, the proportions of patients in each group who utilized the ER will be compared using the standard Chi-square or Fisher's exact test. Associated 95% confidence intervals for these proportions and their differences will be computed using exact methods. For outcome 2b.2, (overdispersed) Poisson regression will be used. For outcome 2b.2, Lachenbruch's two stage procedure for zero-inflated data will also be considered.[25]

Sample Size Considerations. The sample size and power considerations identified for outcomes 2a.1 and 2a.2 are virtually identical for ER utlization.

2c. Quality of Life assessment: We will use the Minnesota Living with Heart Failure Questionnaire[27] (Appendix 4) to assess patient QoL (QoL). While HF will continue to impact the lives of these patients, it is reasonable to believe that proper disease management via telehealth will improve QoL due to earlier exacerbation detection and lowered hospital utilization. We will compare questionnaire results between patients receiving TSM and usual care patients. Measures of QoL are defined as the 3 month QoL score minus the 1 month QOL score, where a positive score indicates a worsening of QoL .

Statistical Methods. A two-sample z-test will be used to compare changes in QoL between groups.

Sample size and power considerations. we expect to enroll 52 patients in each group, a 2-sample z test (80% power) to detect an effect size of 0.39 or greater, which is considered "small" to "medium".[28]

Secondary Analyses: Adjusting for Confounders: Potential confounders will be demographic (age, gender, race, ethnicity, primary language spoken, insurance status (insured vs not-insured), education (high school graduate vs. non-graduate), major co-morbidities (e.g., diabetes Y/N) and functional variables (e.g., heart class, depression symptoms, anxiety symptoms, and caregiver support). All of these measures will be assessed at baseline only. We will use the PHQ4 [19](Appendix 5) to assess symptoms of depression and generalized anxiety disorder as both of these are factors known to have direct impact on cardiovascular outcomes.[29] This is a brief measure (with limited potential participant burden) that has been validated and widely used with heart failure patients.[30,31] It has also been translated into Spanish.[32,33] We will also use a brief measure of caregiver support that assesses assistance with heart failure medical care. The stem question asks if there is someone in participants' lives who helps with heart failure medical care and if answered in the affirmative, participants then indicate their relationship with that person and whether the person lives in the home (Appendix 6). To this end, multiple logistic regression will be used where the outcome variable is hospitalization (yes/no) and the predictor variables are treatment group (telehealth vs. control) on the aforementioned covariates. For number of hospitalizations and length of stay (LOS), analysis of covariance (ANCOVA) will be used if the required distributional assumptions can be met. If not, extension of Lachenbruch's procedure using logistic regression and analysis of variance will be used.

CONFIDENTIALITY

Confidentiality will be protected by assigning to each subject a research data a unique identifier known only to IRB approved personnel.

Storing Documents in Hard Copy

Any documents that contain PHI (e.g., consent forms, link between the ID to subjects' identifiers) will be stored in a locked cabinet within the office of the principal investigator, separately from any de-identified research documents. IRB approved personnel will be the only individuals with access to any research documents containing PHI.

Storing Documents Electronically

Any documents that contain PHI (e.g., link between the ID to subjects' identifiers) will be stored in a password protected computer document/database that will be stored on the NSLIJ network server, separately from the other de-identified research data files. IRB approved personnel will

be the only individuals with access to any research documents containing PHI. De-identified data files will be stored on a password protected computer network.

Storing Documents on Portable Electronic Devices

No PHI will be stored on any Portable Electronic Devices (e.g., laptops, tablets, flash drives, etc.). A laptop computer will be used to collect some anonymous research data. The data will then be transferred to the NSLIJ server using an encrypted flash drive. This de-identified data will be will be removed from the flash drive and then stored separately from unique identifier subject ID link files.

Emailing Data

Research data and participant PHI will not be emailed.

DATA DISCLOSURE/PUBLICATION

Any publications will only include de-identified data.

CONFLICT OF INTEREST

The principal investigator and the co-investigators have no conflict of interest with respect to the research study. Study participants have all signed Conflict of Interest (COI) forms and completed Conflict of Interest training.

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APPENDICES.
See attached 1-6 appendices.