This supplement contains the following items:
1. Original protocol, final protocol, summary of changes.
2. Original statistical analysis plan, final statistical analysis plan, summary of changes
Final protocol (adapted from Black et al. Trials, 2014).

Objectives

The main objective of the BEAT-HF study is to evaluate the effectiveness of this remote care transition intervention in reducing all-cause 180-day hospital readmissions for older adults hospitalized with heart failure. We will also assess 30-day readmissions, all-cause mortality, hospital days, hospital costs, and health-related quality of life. Secondary objectives are to understand the influence of moderating variables such as socioeconomic status, health literacy, and patient comorbidities, as well as the impact of the intervention on intermediate factors such as self-care knowledge and behavior and medication adherence.

Design

BEAT-HF is a prospective, two-arm multi-center, randomized controlled trial being conducted at six academic health systems in California to compare usual care with a telehealth-based care transition intervention for older patients who are discharged home after inpatient treatment for decompensated heart failure. We plan to enroll 1500 patients before hospital discharge, with half randomized to usual care and half to an education/nurse coaching/telemonitoring intervention. Randomization is stratified by medical center. The original BEAT-HF design was a three arm randomized controlled study comparing an adaptation of the Tele-HF protocol, telephone-based health coaching based on the Transitional Care model, and concurrent controls. However, the findings from the Tele-HF study led to a redesign, in which we decided to combine the care transition telephone coaching with telemonitoring.

Site Network

The study is being conducted at six academic medical centers located throughout the state of California. Five of the medical centers are part of the University of California system; the sixth is Cedars-Sinai Medical Center in Los Angeles, which has a mixed model medical staff that includes full time faculty, a multi-specialty group practice, and a large number of independent private physicians. Three of the health systems are major heart transplant centers, and three serve as safety net hospitals for their respective regions.

Study Population

As an effectiveness study, BEAT-HF seeks to enroll a broad range of patients hospitalized with heart failure. Individuals admitted as hospital inpatients or on observation status are eligible if they are age 50 or older, receiving active treatment for decompensated heart failure (defined as initiation of or an increase in diuretic treatment), are expected to be discharged to their home, and are capable of providing informed consent in English, Spanish, Persian or Russian. The study exclusions can be grouped into three main categories: a) patients who do not have the cognitive or physical ability, or access to resources, required to participate fully in the BEAT-HF intervention; b) patients already in a system of care that provides more health provider contacts than the planned intervention; or c) patients whose heart failure is due to a cardiovascular condition that is expected to improve due to medical intervention. More explicitly:
• Patients being admitted from or discharged to a long-term Skilled Nursing Facility (SNF).
• Patients who have previously received any transplant, are being evaluated for a transplant, or are on a waiting list for any transplant.
• Chronic hemodialysis patients (including peritoneal dialysis).
• Patients with dementia. A dementia screener will be administered as part of the consent process.
• Patients who are hospice-bound or expected to expire shortly after discharge.
• Patients who have been previously approached to participate in the study. Patients who indicated a “soft refusal” during the initial approach, may be re-approached upon subsequent readmissions.
• Patients who do not have a working landline or reliable cellular coverage. Patient’s residence should be under a reliable cellular network coverage (as ascertained coverage area maps), or patient must have a landline.
• Patients who cannot use the intervention equipment, such as the weight scale. For example not being able to stand on the weight scale, or if a patient weighs more than 390 pounds (exceeding the tolerance of most devices) he/she will be excluded from the study.
• Patients who cannot identify a usual source of care and who will not be assigned a provider upon discharge will also be included, as clinical follow up and physician communication is an integral part of the study intervention. The usual source of healthcare could be a free clinic, where the patient might not be able to identify a specific provider.
• Patients with the following CVD-related conditions will be excluded:
  o patients with valvular disorders requiring surgical intervention, except for those with incidental valvular disease, who will be included
  o patients with acute myocardial infarction, except for those with demand ischemia, who will be included
  o patients scheduled to receive percutaneous coronary intervention (PCI). For patients being evaluated for PCI, enrollment activities will proceed up through survey and TIBI completion; but enrollment in the study will only occur if the patient is determined to not require PCI.

Multiple sources are used to screen for patients who potentially meet the study’s inclusion criteria. These include lists of patients with heart failure prepared by the hospitals’ Core Measures nurses, lists of patients admitted to cardiology services, pharmacy data on patients receiving intravenous diuretics, and review of admitting complaints, e.g. shortness of breath, pedal edema. Most exclusions are identified through review of electronic medical records or confirmed with the attending physician or bedside nurse, prior to approaching patients in person. Study nurses at each site visit potentially eligible patients in their hospital rooms to explain the study and determine interest in participating. The 6-item Callahan screener is used to evaluate cognitive ability to participate in the intervention. If the patient answers three or more questions correctly, informed consent is obtained and the patient is enrolled. The study nurse administers the baseline survey and then randomizes the patient.

Randomization

Once the baseline survey, TIBI, NYHA classification, and the consent process is completed, the patients will be randomly assigned to either the intervention group or the control group using a web-based computerized random number generator using block randomization within each
enrollment site in the randomization section of the enrollment software. As randomization
occurs upon enrollment, those patients randomized to the control group should not receive
additional services beyond usual care that will be provided to the patients in the intervention
arm.

Intervention

The BEAT-HF intervention consists of three components: pre-discharge heart failure education,
regularly scheduled telephone coaching, and home telemonitoring of weight, blood pressure,
heart rate, and symptoms. The pre-discharge health education is conducted by the study nurse,
who is not part of the usual care team. The nurse guides patients through a low health literacy
booklet that explains heart failure and teaches self-management [i] using the “teach-back”
approach to ensure patient understanding. The pre-discharge education also includes a
demonstration of how to use the remote home telemonitoring equipment and an explanation of
why monitoring physiologic parameters is important for patients. The equipment consists of the
FDA-approved Ideal Life Pod™, a Bluetooth enabled wireless gateway, the Ideal Life Body-
Manager (weight scale), and the Ideal Life BP-Manager, a blood pressure/heart rate monitor
integrated with a device that displays text questions and sends simple text responses. The
hospital-based nurse provides a “warm handoff” to the centralized telephone nurse coaches by
giving patients the name of the nurse who will be contacting them after discharge and showing
her photo. Study nurses use interpreters when needed to communicate with patients who speak
Spanish, Persian, or Russian. When interpreters are not available in person, a three-way
telephone interpretation service is used. Patients take the assembled equipment home, along
with a binder that includes the heart failure education booklet, a one page summary of the
study, a toll-free number for technical support by Ideal Life, a checklist for completion of the 7-
day, 30-day and 180-day telephone surveys, a copy of the upcoming 7-day survey, and copies
of their consent and HIPAA authorization forms.

A call center nurse first contacts each enrolled patient two or three days after discharge from the
hospital to reinforce the pre-discharge health coaching topics. Telephone nurse coaching then
occurs on a weekly basis during the first month post-discharge. The call center nurses have
access to patients’ medical histories and medication records contained in the electronic health
records of each participating medical center. After the first month, nurse coaching calls are
made monthly until the end of the six month study period. All intervention patients receive a
minimum of 9 scheduled telephone coaching calls, generally from the same nurse over time.

Intervention patients are asked to use the Ideal Life Body-Manager and BP-Manager daily to
transmit their weight, blood pressure, heart rate, and responses to three symptom questions.
These wireless devices can be placed anywhere in a patient’s home. They transmit information
to the Ideal Life Pod, which retransmits the collected data via the cellular bandwidth to a secure
server that is accessed daily by the centralized call center nurses. There are two groups of
symptom questions that alternate daily, to reduce respondent burden and minimize repetition.
Readings that exceed predetermined threshold parameters generate a trigger for the call center
nurse, who telephones the patient to investigate. When symptoms are concerning, patients are
encouraged to contact their providers. Table 2 shows the biometric parameters and symptom
responses that prompt the nurse to contact the patient’s physician with an urgent alert. The biometric parameters can be changed by the physician. If deemed necessary, the call center nurses will advise patients to call 911 or go to their nearest hospital emergency room. A call center nurse also calls any patient who has stopped transmitting data to determine the reason and encourage the patient to resume daily monitoring.

Usual Care

After randomization, the site nurse gives patients in the usual care (control) arm a study binder that contains a one page summary of the study, a checklist for completion of the 7-day, 30-day and 180-day telephone surveys, a copy of the upcoming 7-day survey, and copies of their consent and HIPAA authorization forms. Control patients have no further contact with site study nurses or call center nurses. However, they may be exposed to other readmission reduction or chronic disease management programs implemented by hospitals, physician groups, or health plans, such as education about heart failure, pharmacist consultation, and post-discharge telephone calls.

Data Collection and Outcomes

A baseline survey is conducted face-to-face by the hospital study nurse prior to randomization. Patient reported data are collected by telephone surveys conducted at 7 days, 30 days and 180 days after the patient’s initial hospital discharge. Study patients are given a paper copy of the 7 day survey as part of their enrollment packet and receive advance copies of each upcoming survey by mail.

Same-hospital readmissions and hospital days will be obtained from administrative data routinely submitted by the study hospitals to the University HealthSystem Consortium (UHC), a voluntary association of academic medical centers to which all six participating medical centers belong. ED visits to the study hospitals as well as readmissions, hospital days, and ED visits to other California hospitals will be obtained through linked inpatient discharge and ED data from the California Office of Statewide Health Planning and Development (OSHPD), submission of which is mandated by state law. Hospital costs for the study hospitals will be obtained from the UHC data, while costs for admissions and ED visits to non-study hospitals will be estimated from the OSHPD data.

Quality Assurance

An initial in-person meeting was held at which central coordinating center staff provided site coordinator training and reinforcement of the study protocol. Subsequently three additional in-person meetings were held to provide additional site coordinator training and reinforcement of the study protocol. The overall Project Manager and/or the Principal Investigator (from the central coordinating site) visited each site before patients were enrolled. During this site visit, the protocol is reviewed and the local site coordinator demonstrates proficiency in executing the protocol, including identifying potential study participants and using the telemonitoring web site.
All data collected by the site coordinators, enrollment nurses, and centralized call center nurses are reviewed for completeness by the Principal Analyst. All information is entered into an electronic database, with automated checks for data accuracy and completeness.

A Data and Safety Monitoring Board (DSMB) is overseeing the conduct of the study. The committee consists of three researchers from universities not involved in the study. Two members of the UCLA Department of Medicine who are not involved in the study convey data from the study team to the DSMB. Adverse event reports are completed for patient readmissions and deaths and reviewed by the DSMB, with the primary objective of ascertaining any delays in care that occur because patients rely on being monitored by the study.

Compensation

Study participants receive a $10 gift card in the mail following completion of each telephone survey.

Original Sample Size Calculation

Sample size was calculated based on the assumption that the control group would experience no change in the observed baseline 180-day readmission rate of 38%. A sample size of 1,500 (750 per arm) will provide 80% power to detect a relative reduction of 28% in the primary outcome with a significance level of 0.05, after adjusting for within-hospital clustering. We expect to screen approximately 31,500 admissions in order to enroll 1,500 patients.

Primary Endpoint Analysis

The primary outcome measure is the 180-day all-cause readmission rate. Secondary outcomes are the 30-day readmission rate, mortality, ED visits, hospital days, hospital costs, and health-related quality of life (HRQOL).
## Protocol Changes from Original to Final

<table>
<thead>
<tr>
<th>Change</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrollment criteria expanded to include all patients being actively</td>
<td>1/30/2012</td>
</tr>
<tr>
<td>treated for heart failure, instead of just those having a principal</td>
<td></td>
</tr>
<tr>
<td>diagnosis of heart failure. Patients deemed prospectively as not</td>
<td></td>
</tr>
<tr>
<td>having a principal diagnosis of heart failure were being coded as</td>
<td></td>
</tr>
<tr>
<td>heart failure patients after their discharge, due to patients with</td>
<td></td>
</tr>
<tr>
<td>multiple active problems and difficulty determining which is the</td>
<td></td>
</tr>
<tr>
<td>primary problem early in the hospitalization.</td>
<td></td>
</tr>
<tr>
<td>Enrollment criteria expanded to lower the eligibility age to 50 and</td>
<td>1/30/2012</td>
</tr>
<tr>
<td>over, instead of 55 and over.</td>
<td></td>
</tr>
<tr>
<td>Added Farsi as a primary language to English and Spanish</td>
<td>1/30/2012</td>
</tr>
<tr>
<td>Added Russian language as a primary language to English and Spanish and Farsi</td>
<td>3/20/2012</td>
</tr>
<tr>
<td>Allow patients who have reliable cell service, rather than allowing</td>
<td>4/3/2012</td>
</tr>
<tr>
<td>only pts who have reliable T-Mobile cell service,</td>
<td></td>
</tr>
<tr>
<td>Removed weight restriction due to availability of scale to</td>
<td>6/11/2012</td>
</tr>
<tr>
<td>accomodate pts weighing &gt;390 pounds.</td>
<td></td>
</tr>
<tr>
<td>Enrollment criteria modified to accept individuals admitted as an</td>
<td>9/7/2012</td>
</tr>
<tr>
<td>inpatient or for observation</td>
<td></td>
</tr>
<tr>
<td>corrected dementia screener scoring to state pt is allowed to miss up</td>
<td>12/11/2012</td>
</tr>
<tr>
<td>to 2 questions, versus not allowed to miss any questions as was</td>
<td></td>
</tr>
<tr>
<td>originally the threshold.</td>
<td></td>
</tr>
<tr>
<td>Expanded recruitment period to end September 2013 instead of March 2013</td>
<td>3/31/2013</td>
</tr>
</tbody>
</table>
Original statistical analysis plan, final statistical analysis plan, summary of changes

No changes occurred between the original statistical plan and now.

Our analytic approach will use multivariate regression analysis to compare study outcomes between the intervention and usual care groups, adjusting for patient characteristics that can influence resource use and mortality. These analyses will use an intent-to-treat (ITT) framework, within a hierarchical approach using information on medical centers and patients.

Confounding will be assessed by comparing the unadjusted coefficient for treatment condition with the adjusted coefficient. Several of the resource use variables, such as trigger calls and total 180-day hospital readmissions, will likely have non-normal distributions with high skew. As in previous analyses, we will draw upon statistical approaches and models developed for handling this type of data, such as transformation for non-normal distributions; two-part models to handle zero values and skewed non-zero values separately; split-sample techniques to distinguish between different functional forms and to avoid overfitting; and count models (e.g., Poisson and negative binomial models). We will confirm model selection with goodness of fit tests. Although BEAT-HF is not a cluster randomized trial, there is potentially non-random clustering of patient characteristics occurring at the six study sites because we randomized within hospitals. As a result, our quantitative analyses will use mixed effects hierarchical linear models, with two-level models for analyses of patients nested within medical centers, and three-level models for analyses of repeated measurements on patients nested within medical centers.

Power Calculations

We estimated power calculations for a sample size of \( N = 1444 \) with 2 arms with 6 clusters, 722 each arm. Assumptions included alpha 0.05, same N per cluster, ICC = 0.01164. We anticipated approximately a 30% relative reduction in readmission based on prior literature with care transition interventions.

<table>
<thead>
<tr>
<th>Power</th>
<th>Cluster N</th>
<th>Control P(2)</th>
<th>Tx P(1)</th>
<th>Readm Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.8902</td>
<td>120</td>
<td>0.38</td>
<td>0.26</td>
<td>31.60%</td>
</tr>
<tr>
<td>0.8279</td>
<td>120</td>
<td>0.38</td>
<td>0.27</td>
<td>28.90%</td>
</tr>
<tr>
<td>0.7480</td>
<td>120</td>
<td>0.38</td>
<td>0.28</td>
<td>26.30%</td>
</tr>
<tr>
<td>0.6532</td>
<td>120</td>
<td>0.38</td>
<td>0.29</td>
<td>23.70%</td>
</tr>
<tr>
<td>0.5489</td>
<td>120</td>
<td>0.38</td>
<td>0.30</td>
<td>21.00%</td>
</tr>
<tr>
<td>0.4422</td>
<td>120</td>
<td>0.38</td>
<td>0.31</td>
<td>18.40%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>----</td>
<td>----</td>
<td>----</td>
<td>----</td>
<td>-------</td>
</tr>
<tr>
<td>0.3407</td>
<td>120</td>
<td>0.38</td>
<td>0.32</td>
<td>15.80%</td>
</tr>
<tr>
<td>0.2507</td>
<td>120</td>
<td>0.38</td>
<td>0.33</td>
<td>13.20%</td>
</tr>
<tr>
<td>0.1763</td>
<td>120</td>
<td>0.38</td>
<td>0.34</td>
<td>10.50%</td>
</tr>
</tbody>
</table>
BEAT - HF

Operations Manual

October 6, 2011
Introduction
This study compares the effectiveness of implementing care transition interventions on reducing variation in readmissions among hospitalized patients 55 years of age or older with heart failure at six medical centers (five University of California Medical Centers plus Cedars-Sinai Medical Center) over an 18-month period with concurrent controls at the same centers. This project compares an adaptation of existing care transition interventions designed to reduce the implementation costs for the hospitals. The study intervention uses a centralized call center, staffed by nurses and supporting all six medical centers, to provide post-discharge structured telephone monitoring of patients, in conjunction with wireless remote monitoring.

Background & Rationale
Recent studies by the Dartmouth Atlas of Health Care have identified geographic variation in hospital resource use and cost at the end of life among elderly Medicare beneficiaries with chronic illnesses. Reduction of variation in resource use and cost is a key focus for saving costs in the U.S. health care system. One potential area of intervention to reduce hospital resource use and cost variation is readmission rates, and interventions designed to improve the care transition period after hospital discharge have been shown to reduce readmissions and potentially improve morbidity and mortality at the patient level. However, no studies have demonstrated if care transition interventions would result in reductions in variation among hospitals on resource use or health outcomes. In addition, interventions that improve care transitions may be cost-effective at a societal level, but have not been widely disseminated due to implementation costs at the hospital level.

This comparative effectiveness project builds on our prior work examining variation in resource use and mortality among the five University of California Medical Centers plus Cedars-Sinai Medical Center for elderly Medicare beneficiaries hospitalized with heart failure. This work will begin to bridge the current gap between quality improvement research and studies of variation in care, and also provide an opportunity to compare the effectiveness of an existing care transition intervention with an approach that utilizes new technologies. Current studies of variation rarely have the clinical or organizational data to suggest ways to reduce variation between sites, and quality improvement work is often focused on changes at the patient or specific institutional level but not across institutions. Although existing care transition interventions are effective, they have yet to be widely disseminated due to their costs; telemedicine and centralized telephonic interventions that can be simultaneously implemented across a heterogeneous set of hospitals hold promise for potentially reducing these costs.

Trial Objectives
1. Compare the effect of implementing the care transition intervention with concurrent controls on variation in readmissions among patients 55 years of age or older who have been hospitalized with heart failure at the six medical centers.
2. Examine the change in variation over time in readmissions and mortality among hospitalized Medicare beneficiaries with heart failure at the six medical centers.
3. Compare the health benefits and costs of the care transition intervention
Trial Procedures

Inclusion Criteria
Patients 55 years of age or older, who are hospitalized with a principal diagnosis of heart failure.

Exclusion Criteria

• If a patient is admitted from a Skilled Nursing Facility or would be expected to be discharged to such a facility. Looking in the past medical history of the admission note helps to identify that a patient is coming from a SNF.

• History of transplantation or being evaluated as a future transplantation candidate. Looking into past medical history would help to identify if the patient has had transplantation in the past. A patient may be on the waiting list for a transplant at one of the six study medical centers. Patient and/or family members could be asked for confirmation. Please note that this includes any transplant – whether heart, lung, kidney, etc.

• Dementia – If a patient has dementia, he or she will be excluded from the study. This can be found through the admission note or past medical history. In addition, a dementia screener will be administered as part of the consent process.

• Chronic dialysis patients. Review of admission notes or past medical history could help identify chronic dialysis patients. Patient and/or family members could also be asked for confirmation. Another tip would be the presence of a fistula or a dialysis catheter. Please note that patients with peritoneal dialysis could be included in the study but there are few such patients.

• Lack of a working landline or a reliable T-mobile coverage. Patient’s residence should be under a reliable T-Mobile network coverage (as ascertained by T-mobile coverage area maps) if they do not have landline.

• Inability to use the intervention equipment, such as the weight scale. For example not being able to stand on the weight scale, or if a patient weighs more than 390 pounds (exceeding the tolerance of most devices) he/she will be excluded from the study.

Various Considerations:

• If there is doubt or question about including or excluding a patient, the site nurse should contact the site PI or the site study cardiologist and cc Dr. Ong on their email.
• Patients who speak English or Spanish are included.
• Patients who are admitted to the hospital with pacemaker dysfunction could be included.
• Patients who are hearing impaired or visually impaired but can demonstrate to the site nurse that there is someone to help them with study devices are included. It would be up to the nurses’ discretion to make this decision. For example it would be fine if a hearing impaired patient has someone who can answer telephone calls at any time, or if a visually impaired patient has a part time caretaker who can assist with the BP cuff and question pod on a daily basis (the scale has a voice option).

• Patients with coexistent arrhythmia can be included in the study.

• Patients who are transferred in from another site are eligible for participating in the study.

• Patients should be informed that if they travel outside of California or out of the country (e.g., Mexico) for extended periods of time, the call center nurses or research staff might not be able to provide them services and they might need to be withdrawn from the study depending on the site PI’s decision. The California nursing license is not valid out of state. Patients traveling or residing outside of the US will need to be informed that they may incur charges for daily calls from their devices and they will need to provide us with a local number so that the call center nurses can make their calls without incurring international call charges.

• All hospice-bound patients are excluded from the study.

• Patients who cannot identify a usual source of healthcare are excluded. The usual source of healthcare could be a free clinic, where the patient might not be able to identify a specific provider.

• Patients who are on United Health Care heart failure remote monitoring program (or similar programs) are excluded from the study (both control group and intervention group).

• Marginally housed and homeless individuals are excluded unless they are able to handle housing and the maintenance of the technology components and could comply with all aspects of the intervention. Nurse’s discretion and the judgment of those who have approached these patients is important here.

• If a patient cannot comply with the intervention or is unable to use the intervention equipment, he/she will be excluded from the study.

• All surgical valvular patients except for those with incidental disease will be excluded from the study.

• All AMI patients except for those with demand ischemia will be excluded from the study. AMI is defined as cardiac enzyme (trop, CKMB) rise and fall plus
  a) ischemic symptoms
  b) development of Q waves
  c) ST elevations/depressions
  d) PCI
  Documentation of demand ischemia is the chart will count for demand ischemia. If the case is still is unclear, the site nurse should check with the inpatient attending for confirmation.

• All patients receiving PCI will be excluded from the study.
Identifying Potential Patients
As indicated in the inclusion criteria, all patients admitted to the hospital who are 55 years of age or older, and who are admitted for treatment of heart failure should be considered as potential subjects for this study.

Every day, each site will obtain a list of recently admitted patients during the prior day (or prior three days on Mondays). This list is generated in different ways at the different sites, and may be provided by Admission, ER, Cardiology Service Director or from data generated by the Quality Management Services.

This list should include basic information such as name, age, principal diagnosis or symptoms on admission, and MRN. Based on this list and after using medical record number (MRN) and date of birth (DOB) to exclude patients who have been previously approached by the team (either enrolled, excluded, or declined), a preliminary list of potential HF patients will be developed by focusing on the principal diagnosis. All patients with presenting symptoms consistent with HF should be considered for further evaluation.

The following keywords could be used to find patients whose initial principal diagnosis is not HF, but still could be a potential primary case of heart failure: shortness of breath, edema, dyspnea, weakness, or fatigue. Other keywords that might also include patients whose initial principal diagnosis is not HF, but still could be a potential primary case of heart failure: arrhythmias, unstable angina, pneumonia, chest pain, and altered mental status. For these cases that might be HF, the study nurse will need to check the admission note or with the attending physicians to confirm if the suspected patients on the list have HF or not as their principal diagnosis.

Since some HF patients will stay in the hospital for just a short period of time, study nurses should try to identify HF patients admitted the prior day(s) as soon as possible to take necessary steps for enrollment into the study.

Previously Enrolled or Declined to Participate Patients
Patients who have been approached in the past for the study and either enrolled or declined to participate, should not be re-approached. As the enrollment software (Plweb) includes name and medical record number (MRN) of the patient, it can be used to determine whether a patient has been approached before.

If a patient has not been approached on a prior admission (for example if a patient was a weekend admission and was discharged before could be seen), it is ok to approach.

If a patient is identified as being previously enrolled in the study, the study nurse will send an email to the site PD with study ID and new admission date. The site PD will then notify the UCLA PD with this information, who will then relay the information to the overall principal investigator and the data analysis team. If the patient is an intervention patient and the
timeframe is within the six months of enrollment, the call center will be notified.

**Screening evaluation**
The admission notes of all heart failure patients on the finalized daily list will be reviewed by study nurse for exclusion criteria. Patients being admitted from a skilled nursing facility will be excluded. For transplant patients, this is determined by checking the past medical history for receipt of a transplant, if the admission note states the patient is being admitted for transplant evaluation, or if the patient is on the waiting list for a transplant at one of the six study medical centers. The admission note will also be checked for information indicating the patient has dementia.

For the next part, oral consent will be used for screening procedures for the below four subsequent specific items that may exclude an individual from participation: chronic dialysis, lack of a working landline or T-mobile cell service, inability to use the intervention equipment, or dementia. Patients will be approached by the study nurse at each site to complete a brief dementia screener, determine if they are a chronic dialysis patient, and asked whether they have a working landline or T-mobile cell service or whether they can use the intervention equipment. For individuals for whom there are no positive answers on the dementia screener and who are not chronic dialysis patients, can use the intervention equipment (e.g., are not over 390 pounds), and have a working landline phone or T-mobile cell service, consent procedures will be initiated.

**Informed Consent**
At this point, eligible patients will be informed about the study and consent will be requested. The patients should be given approximately one day to decide whether or not they would like to participate in the study. The site nurse will meet with the prospective participants/families to review the consent document(s) and/or provide an oral explanation of the study. Individuals will be given the opportunity to ask questions and/or consult with family and/or friends before making a considered decision about whether or not to participate in the study. Signed consent and HIPAA forms will be obtained from the research participant or Legally Authorized Representative. Signed consent means research participants will be asked to sign and date a written consent form. A copy of the consent and HIPAA form will be kept in patient’s medical record and another copy would be placed in the study binder that will be sent home with the patient.

For non-English speaking patients, if the site nurse does not speak the patient’s language, the site should use an interpreter service (phone or in-person).

The PDs in each site will keep all patients’ signed consent and HIPAA forms in the source document binder in a secure place (locked office, locked drawer). Scanned copies of the signed consent and HIPAA forms will be sent by encrypted email by PDs to the UCLA PD as PDF files on a weekly basis for back up purposes.
Patients will not need to sign the California Bill of Rights since the UCLA IRB does not require a signature for this document and all sites have deferred to the UCLA IRB for the study approach.

**Enrollment**

Once the patient has consented to the study, they are considered enrolled in the study. If a patient is enrolled in the study and at some point did not continue, he/she cannot be re-enrolled.

The patient will be assigned a study ID at this point. Each site will generate its own patients’ study IDs. The study ID is a unique 6-digit code that starts with a number between 1 to 6 which corresponds to the institution to which the patient is admitted (1=UCD, 2=UCI, 3=UCLA, 4=UCSD, 5=UCSF, 6=CSMC). The PIweb system will not let the user to generate a study ID which has been previously created, so there will be no chance of generating duplicate numbers.

**PIWeb**

There is a central enrollment-tracking database (PIWeb), which will contain information important for study nurses, call center nurses and survey research staff. At the beginning of the enrollment in PIWeb, the MRN and the hospital the MRN belongs to is entered in the PIWeb. A unique study ID number will be assigned to each patient by the study nurse who is enrolling the patient. PIweb also contains the procedures for randomization and for communication regarding patients randomized to the intervention.

Once a patient is enrolled, regardless of when the discharge time would be, we need to continue moving forward with study activities. It may be helpful for the site nurse to check with the floor nurses before attempting enrollment to find out if the patient is expected to be discharged shortly.

We should avoid making notes in the patient’s medical record that he/she has been enrolled in this study since that may skew hospital provider (physician and nurse) perceptions of the control vs. intervention patients.

**Best telephone number to use**

All patients need to be asked this information, as both control and intervention patients will receive calls from the survey staff after discharge. This information will be entered in PIWeb for all study patients.

**New York Heart Association Classification (NYHA)**

Heart failure patients experience various symptoms such as limitation in daily physical activity, fatigue, palpitation, or dyspnea. Based on existence and severity of the symptoms, patients are classified into 4 groups, and the classification is recorded in PIWeb for all study patients.
Baseline Survey
Once consent is obtained and the patient is enrolled, the study nurse will administer the baseline survey. The baseline survey is administered by the study nurse using a web-based survey system software while the patient is in the hospital and before randomization is performed. A paper copy should also be provided to patients to assist with completion. Both intervention arm and control arm patients will also be evaluated by baseline survey and follow-up surveys after discharge. Each patient will also be contacted by telephone within 7 days, 30 days and 180 days post-discharge by the survey research staff for other remaining surveys. The survey information will be stored on a secure UCLA server, and only the analysts and the data safety monitoring board (DSMB) will have access to it.

Components of Baseline Survey:
1) REALM-R -- Rapid Estimate of Adult Literacy in Medicine, Revised
To assess how familiar the patient is with some basic medical words.
2) Self-Care of Heart Failure Index
To assess the patient’s ability to care for their heart failure.
3) Minnesota Living with Heart Failure Questionnaire
To assess how much the patient’s heart failure has affected their life.
4) Lubben Social Network Scale
To assess the patient’s social relationship with friends and family.
5) Medicare Care Questions
To assess how much family members and friends are involved in assisting the patient with health care.
6) Geriatric Depression Scale
To assess potential depression.
7) Advance Directive Question

<table>
<thead>
<tr>
<th>Class</th>
<th>Patient Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I (Mild)</td>
<td>No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea (shortness of breath).</td>
</tr>
<tr>
<td>Class II (Mild)</td>
<td>Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, palpitation, or dyspnea.</td>
</tr>
<tr>
<td>Class III (Moderate)</td>
<td>Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, palpitation, or dyspnea.</td>
</tr>
<tr>
<td>Class IV (Severe)</td>
<td>Unable to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken, discomfort is increased.</td>
</tr>
</tbody>
</table>

Table Extracted from Heart Failure Society of America website at http://www.abouthf.org/questions_stages.htm
8) Demographics
9) WHO HPQ - Absenteeism and Presenteeism Short Form
These are questions about patient’s work in order to assess the impact of missed days from work.

**TIBI**
The TIBI (Total Illness Burden Index) questionnaire will be given to patients in both arms of the study while the patient is in the hospital, in order to further assess comorbidities. Patients will be given a hard copy of the TIBI to fill out on their own, but will be assisted upon request.

**Randomization**
Once the baseline survey, TIBI, NYHA classification, and the consent process is completed, the patients will be randomly assigned to either the intervention group or the control group using a web-based computerized random number generator in the randomization section of PIWeb. As randomization occurs upon enrollment, those patients randomized to the control group should not receive additional services beyond usual care that will be provided to the patients in the intervention arm.

**Post-Randomization Steps – Control Group**
The control group will receive the standard of care that is normally provided by the admitting hospital.

Please note:
- No information about these subjects will be sent to the call center.
- NYHA classification will be determined for control group patients and will be entered into PIWeb.
- A contact number and best time to call will be taken from control group patients to be used by survey group for their phone calls after discharge and will be entered into PIWeb.
- No letter will be sent to physicians whose patients are assigned to the control arm of the study.

Following discharge, control patients will be contacted by the survey team during the first week after discharge, 30 days and 180 days after discharge.

Patients in the control arm will receive a control patient study binder to help remind them that they are participating in the study and to remind them that they will be contacted for the over-the-phone at 7, 30, and 180 days post-discharge surveys.

**Content of BEAT-HF Binder for Control Group Patients**
- Consent
-HIPAA
- Study Information (e.g., Survey Calls)
• Space for site specific patient education

If there is any educational material at a site, the control group patients should receive it from their regular nurses. If control group patients ask for further educational material, site study nurses shall refer them to their regular nurses.

Post-Randomization Steps - Intervention Group
Site study nurses will communicate essential information about enrolled intervention patients through PIweb as they go through the intervention procedures. Call center nurses will have the capability to look into PIWeb daily and see all new subjects that have been enrolled and randomized into the intervention arm. Information that is reflected in PIWeb will make the hand-off process as efficient as possible, will help the call center nurse quickly know what education each patient has received and which topics should be reemphasized, and will avoid duplication of effort and manual entry of data.

The following information is captured in the communication section of PIWeb:
• General information about patient such as name, age, MRN, date of discharge, preferred language, phone number, best time to reach, secondary contact number, etc.
• Information about barriers to care and learning
• Completion or not of each of the modularized teaching items, the level of patients’ understanding in each one, and whether a caregiver has also been trained or not.
• Patient’s providers’ information
• Ideal Life serial number for pod, cellular adapter cuff, and scale; and whether the patient has taken the device from hospital or asked that the device be shipped

This information will be gathered and recorded in the system by study nurses during the enrollment, randomization, and post-randomization steps.

We need to be very vigilant that the patients receive the standard of care that should be provided by the regular nurses, and that they are not overlooked by the floor nurses just because they have been assigned to the intervention arm. The study nurse at each site will work with each patient following enrollment and will go through the Education Checklist to ensure the patient is educated about heart failure, self-management, and use and purpose of the Ideal Life equipment.

BEAT-HF Binder for Intervention Patients
Every patient who gets enrolled in the study will receive a BEAT-HF booklet, but the intervention patient binder has more content than the control patient binder. The intervention patients will have the Ideal Life related stuff and the educational material prepared for the intervention group in their booklet.
Content of BEAT-HF Binder for Intervention Group Patients
- Consent
- HIPAA
- Study Information (e.g. Survey Calls)
- Call center nurse names (with photo)
- Educational material
  - Modified UNC booklet
  - Fluid management
  - ZONES
  - Physical Exercise
- Self-Management Examples
  - Weight management (Calendar)
  - Medication List
- Ideal Life Device Information
  - Serial numbers (Cellular pod, cuff, pod, scale)
  - Manual
- Notes
  - Discharge date
  - Discharge weight
  - Follow-up appointment
  - Doctor’s name and phone number
  - Questions for my doctor
  - Hospitalization History

Site study nurse will walk the patient through the booklet and explain and instruct patient on the topics page by page.

Identifying the Call Center Nurses for Each Patient
In order to have a more personal handoff from study nurses in the hospital to the call center nurses who will be managing their post-discharge care, each patient will be paired with a primary call center nurse based on the institution at which they were hospitalized. Upon discharge each patient will be given a sheet in their study binder with the name and photo of the paired call center nurse. The information of other call center nurses would also be provided to each patient on the same sheet of paper, as there will be occasions, e.g., trigger calls or days off, that a call center nurse other than the patient’s usual call center nurse may need to contact them

Barriers to Care
One of the responsibilities of the study nurse is to talk to patients to understand if there are any barriers to care. Some barriers that could potentially impede patients from acquiring appropriate care include:

Language barrier
Indicating barriers to care for each individual will help the healthcare staff and call center nurses to focus on resolving those issues. This information will be entered into PIWeb by the site study nurse so that it is available to the call center nurses.

**Education Checklist**
Site study nurses have a checklist of education topics in PIweb that should be covered before an intervention arm patient is discharged. The overall goal is to complete patient-oriented education, not completing the checklist. The checklist should be used to document what patient-oriented education was completed. The sections in the checklist cover the following items:

- HF basics -- diagnosis & recognizing symptoms
- Daily assessment
- HF medications
- Low-salt eating plan
- Fluid intake
- Physical activity
- Follow-up care
- Study process & equipment

There are specific key elements within each of the above components that are included in the Communication Form. The Communication Form also allows the Study Nurse to indicate who received the education – the patient, the family, or both. It might be someone else in the family who does the cooking or fills out the medication bottles. Call Center Nurses will have full access to the notes that site nurses put in this checklist through PIWeb. The patient's receptiveness to change should be noted and relayed to the CCN, because this may affect their potential trajectory post-discharge.

**Heart Failure Diagnosis and Recognizing Symptoms**
It is important to educate patient in a simple and comprehensive way. For this purpose the educational material will be provided to each patient in terms of a booklet which will help the study nurse to structure teaching to patients.
The main goal is to educate the patient about his or her diagnosis, and key lifestyle measure using teach back approaches.

Here are examples of some teach-back questions:

1) What is the name of your water pills or diuretic?
2) What weight gains would you report to yourself? How do you weigh yourself?
3) What foods have you been told to avoid? Name high sodium foods. (Emphasis should be placed on a low salt education).
4) What changes in yourself would prompt you to call the doctors?

Review the appropriate steps for what to do if a problem arises

The patient should be educated by the study nurse about the appropriate steps for what to do or whom to first call if a problem arises.

The study nurse will discuss with patient:

- A specific plan of how to contact their primary heart failure provider, which could be a cardiologist or a primary care provider depending upon who the patient identified during the enrollment process
- What constitutes an emergency and based on symptoms when to call a doctor versus when to go to emergency room

Medication teaching

The study nurse will educate patient regarding various heart failure medications and the indications of each category:

- What medications to take
- Review each medication’s purpose
- Review dosage and important side effects to watch out for
- Make sure patient has a realistic plan about how to get the medications (use teach back approaches)

Identify key outpatient providers

The outpatient primary heart failure provider is determined for the patient prior to discharge. Most of patients would have already a primary heart failure provider who might be a primary care physician or a cardiologist or other specialist. If the patient has a primary care physician and a cardiologist, the preference is to use the cardiologist as the patient’s primary heart failure provider.

Appointment, Phone Calls, and Surveys

Subject will be asked whether there is a preference in terms of day and time to be called by call center nurses. A sheet with name and photo of three call center nurses will be given to patients to familiarize them with the nurses who will call them after discharge for a better hand-off.
The study nurse will work with each patient to:

- Encourage attendance at post-discharge appointments for clinician follow-up
- Elicit input from the patient on the best time and date of the appointment
- Make sure the patient understands the importance of such services
- Confirm the patient knows where to go and has a plan about how to get to an appointment
- Review transportation options and other potential barriers that might keep patients off their appointments.

The study nurses shall not schedule an appointment for the primary outpatient provider. The goal is to encourage and empower patients to actively inquire and achieve their own healthcare needs. If patients inform the study nurses about a pre-scheduled appointment with their primary HF provider, or the post-discharge appointment has been set, such information could be entered in the Communication Form in the PIWeb.

**Equipment**

The study nurse will educate each patient on use of the wireless remote monitoring devices. Study nurses will instruct patients prior to discharge on how to use the weight scales and BP cuff, and teach the patient on how to use the communication device (i.e. data transmission, text message receipt and sending). The focus should be on relating the self-care they have been educated on with use of the equipment. Patients and/or caregivers will be asked to demonstrate proficiency with using the equipment prior to discharge. Teach back methods should be used to ensure that the patient knows how to use the equipment. Patient should demonstrate putting on the BP cuff, standing on the scale, and going through the box symptom questions. An Ideal Life device user guide with simple language and large font is included in the intervention patient binder.

**Equipment: Connectivity**

The equipment transmits best via landline. If there is no working landline, the equipment could be connected to the provided cellular connector for the purpose of transmitting the results. However, the cellular connector uses T-mobile coverage, and the T-mobile coverage map should be checked if the patient reports not having a landline. Unfortunately cellular connectivity could potentially be disrupted by other wireless devices in the patient’s home like multiple Bluetooth devices. Patients should be warned about the possible interference, one suggestion would be to have the patient turn off other wireless devices when they conduct their daily transmission.

- Landline – the first choice
- Cellular Connector – the second choice, requires T-mobile network coverage, also potential connectivity disruption by means of other existing wireless devices.
- No Ethernet
**Equipment: Troubleshooting/Failure**
In the event of equipment malfunction at the site prior to being sent home with a patient, the Project Director will contact Ideal Life at 1-800-611-2660 for troubleshooting assistance. If equipment is determined to be malfunctioning, complete an Equipment Failure Report and return the equipment to Ideal Life.

Patients will receive prior to discharge the biometric remote sensor devices (weight scale and a BP cuff to measure BP and heart rate), and the communication device, unless they ask for these to be mailed home.

**Equipment: Going Home**
The serial numbers of scale, cuff, cellular adapter, and pod given to the patient must be entered in the patient’s PIWeb system by the site study nurse. These numbers allow the call center nurses to track patients, after entry into the Ideal Life website.

Preferably each patient will take his/her equipment from hospital to home at the time of discharge. However, some patients might ask to receive it by mail. Equipment will not be sent before the patient’s discharge. The site study nurse should confirm patient’s address and preferred time of delivery within the Communication Form. The devices will be sent by Fedex overnight service (for tracking purposes) to patient’s address from UCLA. The device serial numbers will be entered by UCLA.

**Equipment: Site Storage**
We should strive to keep approximately 10 sets of devices at each site. When the number of devices drops below 5, the site PD should be notified so that they can communicate back to UCLA for delivery of more devices. Equipment should not be placed in extreme climates (too hot, too humid) or in direct sunlight or dust. Equipment should be tested upon receipt to ensure they are working properly. If needed, these should be cleaned as noted in the section regarding isolation patients.

**Equipment: Isolation Patients**
Some patients are in isolation. Please follow the below protocol to minimize risk of infection:

1. All equipment items should be cleansed with Clorox (or equivalent) wipes before leaving one patient’s room or hospital, regardless whether patient has been in isolation or not.
   a. Clearly identify and separate areas for clean and used equipment. Maintain storage area cleanliness.
   b. Equipment should be cleaned by wiping down with a cloth dampened with solution of water and mild detergent, or use mild antibacterial wipes. Glass cleaner can be used to clean smudges on plastic or glass surfaces.
2. For isolation patients, in order to minimize contact with items of equipment, consider using a cover where possible (e.g. baggie over scale) if the patient will not be taking the equipment home with them.
Unfinished Pre-Discharge Activity
If there is an unexpected or premature discharge before the study nurse activities are completed, this should be documented by the study nurse in the nurse communication area in PIWeb. The call center nurses will then know what was actually covered during the hospitalization, and can provide patients with additional education or information as needed (e.g., how to set up the Ideal-Life devices). However, we expect most patients to complete most, if not all, of the study nurse activities prior to discharge.

Letter to Primary Heart Failure Provider
Upon randomization to the intervention arm, the Project Director will send a letter to the patient’s primary heart failure provider to let him/her know about the trial and that a new patient has been enrolled in the intervention arm of the study. A summary of the study and the default biometric monitoring parameters will be included in the letter and the provider is requested to let us know if he/she would like to modify the parameters for any given patient. The letter will also indicate the method by which we plan to contact the provider for urgent and for non-urgent matters, and will also request that we be notified if a different method is preferred. Every site will use the project standard letter, but it will be sent from the local site PI’s email address.
**Intervention Post-Discharge Activities**

**Remote Monitoring**

Following discharge, patients will be asked to transmit automated biometric information and symptoms daily to the centralized call center using the communication device. Patients will be instructed to turn on communication device upon waking up in the morning and to turn it off before they sleep at night. As soon as the patient’s personal communication device is switched on, it will remind the patient to perform their daily “Health Check” (e.g. obtain daily weight and vital signs). After being prompted to respond to a series of symptom questions related to their HF status and general health, patients will capture their weight and vital signs using the scale and BP cuff. Information from the remote monitoring system will be automatically downloaded to a secure Internet site for review by the call center nurses, with individuals flagged who have “variance triggers” from daily symptom reports or biometric data that are outside specified parameters (such as a weight gain of greater than 3 pounds in one day or 5 pounds in one week). At the end of six months, patients will be asked to return the monitoring equipment to the medical center using preaddressed packaging with pre-paid postage.

**Call Center**

Call center nurses contact the intervention patients preferably within 3 days of discharge to reinforce patient education, medication and follow-up plans and to conduct problem-solving if necessary. Prior to discharge, all patients are informed to expect a follow-up call within 3 days of discharge. Names and photos of call center nurses will be printed on a sheet of paper and will be given to patient within the intervention patient binder. The call center nurses have access to the PIWeb site (contains Communication Form completed by site study nurses for all patients enrolled into the study), and the patient’s EMR with latest note in the patient’s medical record. Call center nurses will also conduct trigger calls, scheduled weekly calls during the first month, and scheduled monthly calls through six months. The Call Center Nurses should act as a medical coach and not as a pass-through where it makes sense for them to make a clinical decision. Calls might be recorded for quality assurance purposes. The call center will operate also during weekends and holidays, but generally only for responding to trigger calls or, if not avoidable, a scheduled outbound call.

The goal of these calls is not to replace routine management, but to facilitate management. We want to empower intervention arm patients to be proactive in calling their provider when they need to, and for the call center nurse to provide necessary information back to the HF provider. For example, it is not call center nurses’ responsibility to schedule office appointments for subjects. Instead, patients would be encouraged to contact their physician directly and make the appointment themselves (e.g. if needed, coaching patients on what to say when calling the physician’s office). Patients are encouraged to contact their regular care source when needed. Call center nurses could contact other study staff in different sites when having difficulty in contacting provider.

**First Follow-up Call**

The goal is that first call be placed in the first three days after discharge. We are allowing a three day window before or after the third day after discharge. If the first call happens in the
second week, (day 8 through 14), it would be considered the second call out of 4 weekly calls (in this case the first call has been skipped). We will try to minimize stacking post-discharge calls (standard site calls, intervention calls, and survey calls). The expected duration of first call will be approximately 90 minutes in length.

During the first follow-up call the call center nurse will assess any potential problems with care transitions. Any identified issues, medication or otherwise, will be relayed to the primary HF provider, or if different, the primary care provider or provider who will first see the patient following contact. If the patient is having trouble scheduling timely outpatient care, the call center nurses will work with the patient to solve how to set an appointment with the outpatient primary HF provider.

It is recommended to evolve the relationship by asking questions like “is there anything about your health we can help you with today?” Such questions will help demonstrate to the patient that the call focuses on their agenda. Patients should also be asked what is the best day and time to reach them for next calls. This gives patients a sense of empowerment and establishes some sort of buy in for them. Patients are more available when asked for this information.

The following checklist would be used during the first call:

- Review/Reinforce patient education
- Review follow up plans (CCNs will have the ability to tap into EMRs to see if follow-up plans like appointments may have occurred)
- Review specific medications within classes that are important treatments for heart failure (including not using COX-2 inhibitors); call center nurses will ask patients to bring their medications to the telephone to review them and address medication-related problems.
- Review/Reinforce troubleshooting plans (e.g., who should be contacted and under what circumstances)
- Troubleshooting HF and non-HF issues, especially HF issues.
- Make sure patients are adhering to their treatment plans.
- Attend to problems or potential problems as efficiently as possible.
- Reinforce the use of the remote monitoring technology.

If a patient asks a question that call study nurses do not know the answer, they should encourage the patient to call his/her provider. It is discouraged that the nurses call the provider to help the patient with his/her question.

**Weekly calls**
Patients will subsequently be called at a minimum on a weekly basis for a total of at least four telephone contacts during a 30-day period. However, call center nurses may increase the total number of calls during the 30-day period as deemed necessary.

The 4 weekly calls are more or less similar in terms of discussions, but the emphasis would be on those issues that patient needs more education and guidance on (e.g., troubleshooting). It is
estimated that the duration of each weekly call be around 1 hour, but will be dependent on the course of patient’s conversation with the call center nurse.

The following checklist would be used in weekly calls:
• Review/Reinforce patient education
• Review follow up plans
• Review/Reinforce troubleshooting plans
• Troubleshooting HF and non-HF issues, especially HF issues.
• Make sure patients are adhering to the intervention.
• Make attention to problems or potential problems as efficiently a possible.
• Reinforce the use of the Ideal Life technology.

Monthly calls
After the 30-day period, call center nurses will contact the patients on a monthly basis up through six months after discharge. These monthly calls will not be as intensive (e.g., will not explicitly go through each medication as described earlier) as the calls during the first 30-days period, but will be problem-oriented and will provide guidance on any HF management issues raised by the patient and/or caregivers. Reinforcing the use of the Ideal Life technology should be an element of each call.

HF Documentation Tool
The HF Documentation Tool has been developed by call center nurses as a template for the software that will structure their patient calls, support their documentation, and enable them to share information about a patient within their group. It is not intended to be an assessment that will be completed on each call. It is intentionally comprehensive, but not all of the sections will be relevant to all patients on all calls. This template will help to guide their calls and enable them to document and – if a different person has to call the patient back – they can share information amongst themselves.

Inbound Calls
Patients are not encouraged to call the call center. There will be a voice mailbox in place at each site for patients who call and leave messages surrounding non-urgent issues; however, the outgoing message on these voice mailboxes will inform the patients that these mailboxes are checked on an infrequent basis, at most once daily and on weekdays only. Patients are not encouraged to call these numbers, but we understand that some patients may capture the call center phone number on caller id and choose to call the number to try to reach their call center nurse. While all outgoing calls from the call center nurses will be coming from the centralized call center at UCLA, our phone system allows for a local area code phone number (e.g., 415 for san Francisco) to be programmed for display on the call recipient’s caller id. So patients at each site would see a “local” phone number and if they chose to call it, would then reach the local voice mailbox that has been set up at each site for purposes of the study. The local voice mailbox will be checked periodically by the local site PD, and the PD will send an email to the
call center nurse so that they can return the call, if needed. Such calls will be entered into the call center nurse system similar to any other trigger call.

**Non-English Patients**
For non-English speaking patients, if the site nurse does not speak the patient’s language, the site should use an interpreter service (phone or in-person). Similarly, the call center nurses can place calls through a third party on TDD line to communicate with patients who have hearing or speaking problems. TDD allows such patients to read the conversation on a small monitor of their specific telephone gadget and reply back by typing instead of speaking.

**Parameters and Trigger Alerts Protocols**
Call center nurses have an important role in observing the results of daily measurements and taking necessary actions if they encounter a trigger alert or realize that a patient has become symptomatic. There is a set of default thresholds for various biometric parameters that could trigger an alert, and potentially a call to the primary HF provider. Primary HF providers are informed of the default parameters and are given the opportunity to change them up front by contacting the local Project Director, whose name and contact information is provided in the letter sent to physicians upon enrollment of one of their patients in the intervention group.

The table below depicts the parameters that will prompt a call from the call center to the patient:

<table>
<thead>
<tr>
<th>Biometric Parameter</th>
<th>Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBP</td>
<td>SBP &lt; 90 mmHG</td>
</tr>
<tr>
<td></td>
<td>SBP &gt; 160 mmHG</td>
</tr>
<tr>
<td>Heart Rate</td>
<td>HR &lt; 50</td>
</tr>
<tr>
<td></td>
<td>HR &gt; 100</td>
</tr>
<tr>
<td>Weight</td>
<td>Daily gain &gt; 3 Pounds</td>
</tr>
<tr>
<td></td>
<td>Weekly gain &gt; 5 Pounds</td>
</tr>
</tbody>
</table>

The table below depicts the parameters that will prompt a call from the call center to the patient as well as to the primary HF provider:

<table>
<thead>
<tr>
<th>Biometric Parameter</th>
<th>Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBP w/ Symptoms</td>
<td>SBP &lt; 90 mmHG</td>
</tr>
<tr>
<td></td>
<td>SBP &gt; 160 mmHG</td>
</tr>
<tr>
<td>SBP w/o Symptoms</td>
<td>SBP &lt; 80 mmHG</td>
</tr>
<tr>
<td></td>
<td>SBP &gt; 170 mmHG</td>
</tr>
<tr>
<td>Heart Rate w/ Symptoms</td>
<td>HR &lt; 50</td>
</tr>
<tr>
<td></td>
<td>HR &gt; 100</td>
</tr>
<tr>
<td>Heart Rate w/o Symptoms</td>
<td>HR &lt; 40</td>
</tr>
<tr>
<td></td>
<td>HR &gt; 110</td>
</tr>
<tr>
<td>Weight w/ Symptoms</td>
<td>Daily gain &gt; 3 Pounds</td>
</tr>
<tr>
<td></td>
<td>Weekly gain &gt; 5 Pounds</td>
</tr>
</tbody>
</table>

These thresholds could be changed for a particular patient based on the discretion of the primary HF provider. Initially after a patient’s discharge, since call study nurses are not familiar with the patient’s health condition, they will call the patient to assess each trigger alert. Talking to patient over the phone, they will assess the patient’s condition and decide whether they
should recommend the patient call their primary HF provider, also call the primary HF provider, initiate a 911 call, or make some other recommendations to the patient.

There are also some general and specific symptom questions that each patient will answer every day prior to performing the above-mentioned tests. These symptom questions help the nurses to evaluate the general condition as well as the heart performance of the patient, and may trigger a call to the primary HF provider if biometric thresholds are met.

<table>
<thead>
<tr>
<th>Question</th>
<th>Trigger</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you felt more short of breath in the last day?</td>
<td>Yes</td>
</tr>
<tr>
<td>Have you noticed more swelling in the last day?</td>
<td>Yes</td>
</tr>
<tr>
<td>Did you wake up more short of breath last night?</td>
<td>Yes</td>
</tr>
<tr>
<td>Did you sleep in a chair, or propped up on pillows, more than usual last night?</td>
<td>Yes</td>
</tr>
<tr>
<td>Have you had any light-headedness or dizziness in the last day?</td>
<td>Yes</td>
</tr>
<tr>
<td>Today, would you say your health is excellent, very good, good, fair, or poor?</td>
<td>Poor</td>
</tr>
<tr>
<td>Compared to yesterday, would you say you are feeling about the same, better, worse, or much worse?</td>
<td>Much worse</td>
</tr>
</tbody>
</table>

Like biometric parameters, the call center nurses would call the patient to assess and verify the condition. If they find the patient is symptomatic they would contact the primary HF provider to let him/her know.

Whenever the call center nurse calls the primary HF provider, she would discuss the trigger alert and could ask whether the provider tends to set a new threshold based on patient’s specific conditions.

Depending on patient’s symptoms and level of exacerbation, the call center nurse may call 911 and advise patient to refer to the EMS as soon as possible. In less severe conditions but still urgent, the nurse may contact patient’s physician through pager or phone. In non-emergent situations, the physician may be notified through email or other means on a non-urgent basis. In sites that have installed EPIC EMR system, physicians can get notified quickly through EPIC messages system.

<table>
<thead>
<tr>
<th>Situation</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-urgent condition</td>
<td>Non-urgent physician notification</td>
</tr>
<tr>
<td>Urgent condition</td>
<td>Urgent physician notification by pager/call</td>
</tr>
<tr>
<td>Emergent condition</td>
<td>Call 911</td>
</tr>
</tbody>
</table>

Since the Call Center Nurses would have access to each patient’s EMR, they can look into recent hospitalization records and judge to some extent whether the readings are something that should be expected or not.

Some examples of emergent and urgent conditions in the below table:
Implantable Cardioverter / Defibrillator (ICD) Protocol
The following protocol should be considered if a patient notifies call center nurses about receiving shocks by his/her ICD:

A. ICD shock one time. Whenever patient reports to CCN their ICD device fired once
   1) If patient is asymptomatic:
      a) CCN should instruct patient to contact ICD Clinic or HF provider as soon as possible to discuss shock event and arrange appropriate follow-up
      b) CCN should contact ICD Clinic or HF provider concerning report of ICD shock and relay information about patient's current status & instructions given to patient to call ICD clinic/provider.

   2) If patient reports symptoms [i.e. chest pain, pressure, shortness of breath, abnormal heart beat, dizzy, confused or not feeling well]
      a) CCN should caution patient not to attempt to drive self to ED
      b) Based on patient's symptoms, CCN should advise patient to either have someone drive them immediately to the nearest ED or call "911"

<table>
<thead>
<tr>
<th>Examples of Emergent Condition</th>
<th>Examples of Urgent Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Irregular or rapid pulse</td>
<td>• Difficulty in sleeping</td>
</tr>
<tr>
<td>• Increased dyspnea</td>
<td>• Increased swelling in ankle</td>
</tr>
<tr>
<td>• Dyspnea while seated</td>
<td>• Increased weakness or fatigue</td>
</tr>
<tr>
<td>• Extreme sweating</td>
<td>• Frequently dry cough</td>
</tr>
<tr>
<td>• Chest pain or chest pressure</td>
<td>• Increased wheezing</td>
</tr>
<tr>
<td>• Change in mental status</td>
<td>• Weight gain &gt; 3 pounds a day</td>
</tr>
<tr>
<td>• Blue lips, tongue, or fingernail beds</td>
<td>• Weight gain &gt; 5 pounds a week</td>
</tr>
<tr>
<td>• Inability to speak due to dyspnea</td>
<td>• Loss of appetite, indigestion</td>
</tr>
<tr>
<td>• Extreme fatigue</td>
<td>• Light headedness/dizziness</td>
</tr>
<tr>
<td>• Frothy pink or copious white sputum</td>
<td>• Upper respiratory infection with fever and cough</td>
</tr>
<tr>
<td>• Feeling of suffocation</td>
<td>• One ICD shock with symptoms or multiple ICD shocks</td>
</tr>
<tr>
<td>• Sudden increase swelling in legs, feet, or abdomen</td>
<td>• One time ICD shock without symptoms</td>
</tr>
</tbody>
</table>
c) CCN should contact HF provider and ICD Clinic concerning events and patient disposition

B. ICD device fired two or more times
1) CCN should advise patient to have someone drive them immediately to the nearest ED or call "911"

Making changes in biometric parameters
If primary HF provider decides to adjust his/her own desired triggers based on patient’s condition, call center nurses will let Dr. Ong know by email. Changes will be effective immediately. Individualizing the parameters will minimize unnecessary alerts and trigger phone calls.

Primary HF Provider Unresponsive to Calls and Messages
In case the primary HF provider is unreachable by any means the call center nurses can ask the local site PI to help them reach the primary heart failure provider. Many physicians’ contact information like pagers, backline office phone numbers, and email addresses are available through the EMR system of each site, and electronic lists have been put together for the sites where this information is not available online.

Missing Patient Readings
If a patient’s readings do not show up the call center nurses will try to contact the patient up to 3 times in one day. If they can not reach a patient after making 5 phone calls at different times in 2 days, they will call the secondary contact to inquire about the patient’s condition.

Readmission Notification
If a patient who is already on the trial gets hospitalized, daily readings would cease, which is a trigger for call center nurses to call patient to inquire the reason of stopping daily results. If call center nurses get notified of a patient’s hospitalization, they will document it in their records. Also the primary HF provider should be informed about the patient’s readmission.

Equipment Failure
In case of failure of the Ideal Life devices, patients should contact the Ideal Life toll free customer service line directly at 1-800-401-5101 for assistance. Customer service is available Monday through Friday, 6am to 5pm PST.

Subject Traveling Outside of California
In case an individual travels outside of California, he/she can carry the device and continue measurements, however the results will not be transmitted to Ideal Life server unless the patient also brings along the pod. Pods are usually not carried by patients while they are travelling. Call center nurses should avoid calling a patient if she/he is travelling abroad, and should try to identify an alternate time to call (before or after the trip). We should avoid incurring international calls if patients are traveling out of the country.

Transfer Call to EMS in Emergent Situations
In an emergent situation when the patient is alone, the call center nurse would remain on the line until the patient could talk directly with the EMS. When CCN transfers the patient's call directly to EMS dispatcher, the CCN will immediately provide the address where the patient is physically located as well as the patient’s phone number. CCN will then confirm the EMS dispatcher does not need any further information from the CCN before disconnecting from the call. CCN will immediately notify the patient’s HF provider and the overall Principal Investigator (Dr. Ong).

Handling Emotional Distress and Suicide Risk
Call center nurses or research staff shall immediately notify the overall Principal Investigator (Dr. Ong) by pager and/or phone if they encounter a patient having suicidal thoughts and also contact the National Suicide Hotlines at 800-784-2433, 800-273-8255, or 800-799-4889 (Deaf Hotline). If the patient is still in the hospital, study nurses should inform the site principal investigator as well as hospital staff about patient’s condition.

Patient Abuse Issues
If the call center nurses come across a case of patient abuse they should contact the primary care provider to inform him/her about the situation. It can be difficult to verify the validity of an abuse claim based on a telephone call. Based on their discretion, the nurses may also need to call adult protective services. The overall Principal Investigator (Dr. Ong) will also be notified of all such situations.

Research Related Injury, Patients Concerns or Complaints
In the event of a research related injury, or if patients have any questions, comments or concerns about the research, they are advised to immediately contact the local site principal investigator or Dr. Michael Ong at 310-794-0154, 911 Broxton Avenue, Los Angeles, CA 90024.

If patients wish to ask questions about their rights as a research participant or if they wish to voice any problems or concerns they may have about the study to someone other than the researchers, they should call the Office of the Human Research Protection Program at (310) 825-7122 or write to Office of the Human Research Protection Program, UCLA, 11000 Kinross Avenue, Suite 102, Box 951694, Los Angeles, CA 90095-1694.

Withdrawal of Participation
Patients may withdraw by their own decision at any time without consequences of any kind. The investigator may withdraw patient from participating in the research if circumstances arise which warrant doing so. If a patient is no longer able to complete a telephone survey, he/she may have to drop out, even if he/she wants to continue. The principal investigator will make the decision and let the patient know if it is not possible for him/her to continue.

Post-Discharge Surveys
All individuals (in both the control and intervention groups) will be surveyed after discharge through phone calls by research staff. The first post-discharge survey will be administered at one week, at 30 days, and at 180 days.
A hard-copy of each survey will be sent in advance to the patient’s home address so that they have a chance to review the questions prior to the call. Patients may refuse to answer any questions that they do not want to answer and still remain in the study.

It is anticipated that one hour will be needed for each phone call.

**Components of the first Post-Discharge (7-Day) Survey:**
1) CTM  
2) Hospital Questions  
3) ER Questions  
4) Medical Visit questions  
5) Geriatric Depression Scale – Short form  
6) Minnesota Living with Heart Failure Questionnaire  
7) Self-Care of Heart Failure Index  
8) MMAS-8 (for assessment of Medication Adherence)

**Components of the second and third (last) Post-Discharge Surveys:**
1) Hospital Questions  
2) ER Questions  
3) Medical Visit questions  
4) Geriatric Depression Scale – Short form  
5) Minnesota Living with Heart Failure Questionnaire  
6) Self-Care of Heart Failure Index  
7) MMAS-8  
8) LUBBEN SOCIAL NETWORK SCALE – 6  
9) MEDICAL CARE QUESTIONS  
10) WHO HPQ - Absenteeism and Presenteeism Short Form

**Patients’ Reimbursement**
Patients will receive a $10 gift card for completing each of three telephone surveys, up to a total possible of $30 for completing all three telephone surveys. The gift card will be sent to the patient’s home address by research staff after completion of each survey, and they should expect to receive the cards in 2 to 4 weeks.

**Confidentiality & Patients Privacy**
- The information that will be reviewed is the minimal necessary to identify potential research participants for this research.  
- The information that will be obtained for identification of participants will not be reused or disclosed outside the research team, except as required by law.  
- All study personnel will comply with HIPAA regulations.  
- All participants will sign a HIPAA Research Authorization for Release of Personal Health Information for Research.  
- To protect confidentiality of all electronic data, encryption or password protection software
and secure network servers will be used to store data in this study.

For patients providing information by paper survey, this will be done in their room during hospitalization. For patients providing information by computer-assisted telephone interview, this will be obtained from patients in their homes. The staff conducting computer-assisted telephone interviews and the centralized call center will be housed in areas where private calls can be conducted.

All patient-identifying information will be kept confidential. The survey research group will use one set of identifiers (Field IDs) in their contacts with participants. Our programmer will receive field data from the survey research group and transform the Field IDs to another set of IDs (Analytic IDs) before the data are available to the investigators. The file that links the 2 IDs will be secured and accessible only to the programmer and the principal investigator. Identifiable hard copy data will be maintained separately by the survey research group with limited access and kept only as long as needed to maintain consent files or to contact patients for follow-up surveys.

**End of Trial**

The total time of study for each subject is 6 months after discharge. At the end of trial intervention patients will be asked to return the devices to UCLA study center, through pre-paid shipping materials that will be sent to them. All devices upon return will be disinfected.
BEAT-HF
Study Protocol Guide

Revised
March 2014
BEAT-HF Study Protocol Guide

Table of Contents

Introduction

Study Software Systems and Online Documentation

Trial Procedures: Patient Screening, Enrollment, and Randomization

Trial Procedures: Post-Randomization Steps – Control Group

Trial Procedures: Post-Randomization Steps – Intervention Group

Trial Procedures: Intervention Equipment

Trial Procedures: Post-Discharge Activities – Control Group

Trial Procedures: Post-Discharge Activities – Intervention Group

Trial Procedures: Follow-up Telephone Surveys

Trial Procedures: Local Site and UCLA Study Center Operations

Patient Confidentiality and Questions about the Study

Appendices:
   A. Survey Instruments
   B. New York Heart Association Classifications
   C. Intervention Group – Pre-Discharge Education
   D. Study Diagram
### Introduction

**Study Summary**
This comparative effectiveness study compares the effectiveness of implementing a care transition intervention on reducing variation in readmissions among hospitalized patients 50 years of age or older with heart failure at six medical centers (five University of California Medical Centers plus Cedars-Sinai Medical Center) over a two-year period with concurrent controls at the same centers. The study compares an adaptation of existing care transition interventions, the Transition Coach and Re-Engineering Discharge programs, designed to reduce the implementation costs for the hospitals. The study intervention uses a centralized call center, staffed by nurses and supporting all six medical centers, to provide post-discharge structured telephone monitoring of patients, in conjunction with wireless remote monitoring.

**Background & Rationale**
Recent studies by the Dartmouth Atlas of Health Care have identified geographic variation in hospital resource use and cost at the end of life among elderly Medicare beneficiaries with chronic illnesses. Reduction of variation in resource use and cost is a key focus for saving costs in the U.S. health care system. One potential area of intervention to reduce hospital resource use and cost variation is readmission rates, and interventions designed to improve the care transition period after hospital discharge have been shown to reduce readmissions and potentially improve morbidity and mortality at the patient level. However, no studies have demonstrated if care transition interventions would result in reductions in variation among hospitals on resource use or health outcomes. In addition, interventions that improve care transitions may be cost-effective at a societal level, but have not been widely disseminated due to implementation costs at the hospital level.

This comparative effectiveness project builds on our prior work examining variation in resource use and mortality among the five University of California Medical Centers plus Cedars-Sinai Medical Center for elderly Medicare beneficiaries hospitalized with heart failure. This work will begin to bridge the current gap between quality improvement research and studies of variation in care, and also provide an opportunity to compare the effectiveness of an existing care transition intervention with an approach that utilizes new technologies. Current studies of variation rarely have the clinical or organizational data to suggest ways to reduce variation between sites, and quality improvement work is often focused on changes at the patient or specific institutional level but not across institutions. Although existing care transition interventions are effective, they have yet to be widely disseminated due to their costs; telemedicine and centralized telephonic interventions that can be simultaneously implemented across a heterogeneous set of hospitals hold promise for potentially reducing these costs.

**Study Objectives**
1. Compare the effect of implementing the care transition intervention with concurrent controls on variation in readmissions among patients 50 years of age or older who have been hospitalized with heart failure at the six medical centers.
2. Examine the change in variation over time in readmissions and mortality among hospitalized Medicare beneficiaries with heart failure at the six medical centers.
3. Compare the health benefits and costs of the care transition intervention
Study Software Systems and Online Documentation

PIWeb
The study’s central enrollment-tracking database, PIWeb, contains important information for study nurses, call center nurses, survey team members, and other study research staff. To begin tracking a screened patient in PIWeb, the patient’s MRN, admission hospital, and a unique participant ID (PID) number that is assigned by the study nurse, are entered into the system. PIWeb also contains the procedures for randomization and for communication between the pre-discharge and post-discharge study staff regarding all patients, but particularly for those randomized to the intervention including for communication among the call center nurses. PIWeb data is stored on a secure UCLA server, and access to this system is controlled via login and password.

Online Survey System

Patient Surveys – Both intervention arm and control arm patients will be evaluated by baseline survey, and follow-up surveys after discharge. The baseline survey is administered by the study nurse while the patient is in the hospital during the index hospitalization, and the three follow up surveys are conducted via telephone by a survey team member. Each patient will be contacted by telephone within 7 days, 28 days and 180 days post-discharge by the survey research staff for the telephone surveys. The survey information will be entered using our study online survey system for both the baseline and follow up surveys.

TIBI – Following administration of the baseline survey, the Total Illness Burden Index (TIBI) questionnaire will be given to patients in both arms of the study while the patient is in the hospital, in order to further assess co-morbidities.

Survey system data is stored on a secure UCLA server, which can only be accessed by the staff conducting the surveys, project team study analysts, and the data safety monitoring board (DSMB). Access to this system is controlled via login and password.

Ideal Life Portal

Patients’ readings are stored on Ideal Life’s secure server. Call center nurses and other approved study staff need to login to the server with their username and password to access the portal. Each intervention patient upon enrollment in the study will have a unique account in the Ideal Life portal that will house the biometric readings taken by the patient during the course of study. The readings are automatically transmitted to the portal by means of the communication device (cell pod) that is given to each enrolled intervention patient. All readings are considered part of patient’s medical record and will be protected as such on the Ideal Life portal. The readings are exportable to Excel spreadsheets for analysis purposes.

Call Center Nurse Call Logs and Notes
The call center nurses document their calls to patients in PDF forms that have been developed for this purpose. The forms are completed on the nurses’ hard drives, and then encrypted and password protected and copied to the I-drive for storage after they are completed. There are three kinds of PDF form that will be used to facilitate documenting these communications:

- The ClinicalDoc form will be used to document scheduled calls and trigger calls. This 9 page form lets the nurses ask about various clinical aspects of the patient’s health condition on a systematic fashion.
- The PhoneDoc form which is a one page form will be used to document some of the trigger calls and all sort of other calls that nurses make such as calls to secondary contact, follow up call to patient or provider, or call to Ideal Life company.
- The MedLog form is used to document all the medications patients use during the course of study.

**Survey Team Tracking Spreadsheets**

**Contact list** – This spreadsheet contains the most current patient contact information, including phone numbers and address, secondary contacts, language preferences, and any notes about the patient and/or his/her living arrangements that might help with the calls. It is stored on the I-drive.

**Call logs** – Call attempts are stored in this spreadsheet on Google docs.

**Gift card tracking**

- The dates that gift cards are sent to each participant are tracked in the call log spreadsheet on a separate sheet.
- The gift card numbers list is stored locally on the hard drive of the study team member responsible for tracking and mailing gift cards and for managing gift card inventory.

**I-Drive Administrative Tracking Spreadsheets**

**Inventory Tracking** – A spreadsheet is maintained and updated daily to indicate the level of equipment inventory for each type of equipment – scales, BP managers and cuffs, and cell pods (transmission/communication device) – at each of the sites. Total counts as well as specific equipment serial numbers are kept in this spreadsheet.

Another spreadsheet is maintained to track patients who have completed the study or are no longer using the tele-monitoring equipment for various reasons, and the status of their equipment return. Upon completion of the six month study enrollment period, participants will be asked to return equipment to UCLA, where it will be disinfected and tested and prepared for re-use; and this spreadsheet is used to track the status of the equipment return package to and from the patients. Equipment returned from patients who have withdrawn from the study or withdrawn from tele-monitoring and from patients who have expired before completing the six month study, will be tracked here as well.

**Data Modifications** – A spreadsheet is maintained containing data cleaning changes that were made by the study’s data analysts or the UCLA project director to data in PIWeb, such as correction of data entry errors, removal of duplicate records, etc.
Adverse Event (AE) Tracking – A spreadsheet is maintained containing AEs (readmission or expiration) for patients during their six month study enrollment period. In addition, copies of all AE forms from all of the sites are kept in zip drive format on the I-drive.

HIPAA forms and Consent forms – Scanned PDF copies of signed HIPAA and signed Consent forms from every patient are stored on the I-drive and organized by document type and site.
**Trial Procedures: Patient Screening, Enrollment, and Randomization**

**Inclusion Criteria**
Patients 50 years of age or older who are admitted as an inpatient or for observation at any of the six academic medical centers and are being actively treated for heart failure.

**Exclusion Criteria**
- Patients who have been previously approached to participate in the study and were either enrolled or declined to participate.
  - Patients who indicated a “soft refusal” during the initial approach may be re-approached upon subsequent readmissions.
    - Checking the *Why did the patient not consent?* field for "soft refusal" will identify patients who might be able to be reapproached on a subsequent admission
- Patients being admitted from or discharged to a long-term Skilled Nursing Facility (SNF) stay.
  - Looking in the past medical history and the admission notes helps to identify that a patient is coming from a SNF. In addition, Case Manager and physician notes can help identify pts that will be discharged to a SNF
- Patients who have previously received a transplant, are being evaluated for a transplant, or are on a waiting list for a transplant. Please note that this includes any transplant – whether heart, lung, kidney, etc.
  - Transplant exclusion can be determined by:
    - Looking into past medical history to identify if the patient is an organ transplant recipient.
    - A patient may be on the waiting list for a transplant at one of the six study medical centers. Although being on the waiting list for a transplant at any medical center is an exclusion, we are better able to check among our study sites.
    - Patient and/or family members could be asked for confirmation.
  - If during the course of the hospitalization, the patient is determined ineligible for a transplant or does not want to pursue a transplant, then the patient can become eligible for our study. Because these patients are often discharged shortly after evaluation, there may be only a small window for approaching and enrolling. So, subject to the judgment of the local study team, these patients can be either:
    - closely monitored for evaluation completion/determination and then approached if it is determined that the pt will not be pursuing a transplant, or
    - approached up through and including survey and TIBI, but they cannot be randomized until we know they will not be pursuing a transplant.
- Patients with dementia. If a patient has dementia, he or she will be excluded from the study.
  - This can be found through the admission note or past medical history.
  - In addition, a dementia screener will be administered as part of the consent process.
• Chronic dialysis patients. Please note that patients with peritoneal dialysis could be included in the study, although there are few such patients.
  o Review of admission notes or past medical history could help identify chronic dialysis patients.
  o Patient and/or family members could also be asked for confirmation.
  o Another indicator would be the presence of a fistula or a dialysis catheter.
• Patients who are hospice-bound or expected to expire shortly after discharge.
• Patients who do not have a working landline, Ethernet, or reliable cellular coverage. Patient’s residence should be under a reliable cellular network coverage (as ascertained coverage area maps), or patient must have a landline or Ethernet access.
• Patients who are unable to comply with the intervention. For example, if the patient is unable to stand on the weight scale.
• Patients who cannot identify a usual source of care and who will not be assigned a provider upon discharge will also be excluded, as clinical follow up and physician communication is an integral part of the study intervention. The usual source of healthcare could be a free clinic, even if the patient is not able to identify a specific provider.
• Patients with the following CVD-related conditions will be excluded:
  o patients with valvular disorders requiring surgical intervention, except for those with incidental valvular disease, who will be included
  o patients with acute myocardial infarction, except for those with demand ischemia, who will be included
  o patients who have received or are scheduled to receive a percutaneous coronary intervention (PCI) or CABG during this admission. For patients being evaluated for PCI, enrollment activities will proceed up through survey and TIBI completion; but enrollment in the study will only occur if the patient is determined to not require PCI.

Other Eligibility Considerations
• If there is doubt or question about including or excluding a patient, the site nurse should contact the site PI and/or the site study cardiologist, and cc Dr. Ong on their email.
• Patients who speak English, Spanish, Farsi, or Russian are included. On site translation services should be used for enrollment activities. Patients speaking a language other than these can be considered on a case by case basis.
• Patients who are admitted to the hospital with pacemaker dysfunction can be included in the study.
• Patients who are hearing impaired or visually impaired but can demonstrate to the site nurse that there is someone to help them with study devices can be included. It is up to the nurses’ discretion to make this decision. For example, a hearing impaired patient who has someone who can answer telephone calls at any time, or a visually impaired patient with a part time caretaker who can assist with the BP cuff and symptoms questions on a daily basis (the scale has a voice option), can be included in the study.
• Patients with coexistent arrhythmia can be included in the study.
• Patients who are transferred in from another site are eligible for participation in the study.
• Patients should be informed that if they travel outside of California or out of the country for extended periods of time, the call center nurses will not be able to provide them with services, as the California nursing license is not valid out of state; and the patient might need to be withdrawn from the intervention portions of the study depending on the site PI’s decision, primarily based on the length of stay outside of California.

• Patients who are on United Health Care’s heart failure remote monitoring program (or similar programs) are excluded from the study.

• Marginally housed and homeless individuals are excluded from the study unless they are able to handle housing and the maintenance of the remote monitoring equipment and can comply with all aspects of the intervention. It is up to the nurse’s discretion and the judgment of those who have approached these patients to make this decision.

Identifying Potential Patients
As indicated in the inclusion criteria, all patients admitted to the hospital as an inpatient or for observation who are 50 years of age or older and who are being actively treated for heart failure should be considered as potential subjects for this study.

Each day, the site project manager and study nurse will obtain a list of recently admitted patients for the prior day, or prior three days in the case of Monday’s screening. This list is generated in different ways at each site, and may be provided by Admission, ER, the Cardiology Service Director or from data generated by the Quality Management Services. The list should include basic information such as name, age, principal diagnosis and/or symptoms on admission, and MRN.

From this list, and after using medical record number (MRN) and date of birth (DOB) to exclude patients who have been previously approached by the team, a preliminary list of potential heart failure patients will be developed based on each patient’s diagnoses on admission, including heart failure as well as other presenting symptoms consistent with heart failure — e.g., shortness of breath, dyspnea, fatigue, weakness, edema — or being evaluated for conditions that may precipitate hospitalization for heart failure such as atrial fibrillation. Other keywords that might also be used to identify a potential heart failure admission include: arrhythmia, unstable angina, pneumonia, chest pain, and altered mental status. For the remaining potential HF patients, the study nurse will then check the admission notes and confirm with patients’ attending physicians whether the patient, particularly for those only with presenting symptoms or precipitating conditions, should be considered as being actively treated for HF. All patients with presenting symptoms consistent with heart failure should be considered for further evaluation, and at this point should be entered into PIWeb and/or into the study records of potentially eligible patients.

Next, the study nurse will determine from patient charts and/or discussion with the attending physician if the patient should be excluded for any of the following reasons: patients with valvular disorders requiring surgical intervention (except for those with incidental valvular disease, who will be included), acute myocardial infarction (except for those with demand ischemia, who will be included), percutaneous coronary intervention (PCI), expected to enroll in hospice or expire shortly after discharge.
Since some heart failure patients will stay in the hospital for just a short period of time, study nurses should try to identify heart failure patients admitted the prior day(s) as soon as possible to take necessary steps for enrollment into the study and having time to complete all pre-discharge enrollment activities.

**Patients who have been previously approached**

Patients who have been approached in the past for the study and either enrolled or declined to participate, generally should not be re-approached. PIWeb, our online screening and enrollment system, includes name and medical record number (MRN) of the patient, so it can be used to determine whether a patient has been approached before. In some cases, however, it may have been noted in the "Why did the patient not consent?" box that the patient gave a “soft refusal”, meaning for example that the time was just not right or the diagnosis was too new to absorb; and the study nurse and site PI can make a determination on a case by case basis if it is appropriate to re-approach a patient.

If a patient was determined eligible on a prior admission but was not approached – for example, if a patient was discharged before he/she could be seen – it is ok to approach the patient on a subsequent admission where they are again being actively treated for HF.

If a patient is identified as previously enrolled in the study and the patient is still within the six month study enrollment period, this is considered a readmission and the study nurse will fill out an adverse event (AE) report and send it in an email to the site project director and the UCLA study team member responsible for AE tracking. The UCLA project director will then relay the information to the overall principal investigator and the survey team. If the patient is an intervention patient and the timeframe is within the six months of enrollment, the call center will be notified as well. The site project director will monitor the patient’s EMR for discharge from this readmission, and will update *Enrollment Status* and *Discharge Date* PIWeb when the patient is discharged.

**Of special note for UCLA and CSMC**

Because these institutions are located geographically close to one another, there is some overlap between patients who may be admitted to either facility. Part of the daily screening process should include checking patient names against the names of patients enrolled at the other site to avoid enrolling a patient at one site that already has been enrolled at the other. If the study nurse or project director suspects a patient may have been enrolled at the other site, or if a patient is enrolled at their site who has a physician at the other site, an email should be sent to the project director at the other site requesting verification and/or letting them know of the possible overlap.

**Screening evaluation**

The admission notes of all heart failure patients on the finalized daily list will be reviewed by the study nurse for exclusion criteria for being admitted from or discharged to a long-term Skilled Nursing Facility (SNF), transplant, and dementia. If the patient does not meet any of these exclusion criteria, the patient or the patient’s decision maker will be approached to determine if the patient should be excluded from the study based on subsequent criteria: chronic dialysis; hospice-bound; lack of a working landline or reliable cell service; inability to use the intervention
weight scale or otherwise unable to use the intervention equipment; inability to identify a usual source of care (free clinic is acceptable) and no provider being assigned upon discharge; or dementia, by administering a dementia screener (patients are eligible if they correctly answer four or more questions on the six item screener). For non-English speaking patients, if the study nurse does not speak the patient’s language, the site should use an in-person interpreter service or telephone interpreter service.

Patients are entered into PIWeb by selecting “BEATHF V2” from the home page and then proceeding to “Collect or Enter Data” to enter the patient’s MRN, admission hospital, and a unique participant ID (PID) number assigned by the study nurse. Each site will generate its own patients’ sequential PIDs. The PID is a unique 7-digit code that starts with a number between 1 to 6 which corresponds to the institution to which the patient is admitted (1=UCD, 2=UCI, 3=UCLA, 4=UCSD, 5=UCSF, 6=CSMC). A site may choose to add an additional identifying digit in the second position, e.g. 61xxxxx and 62xxxxx, to identify the person doing the screening. If a patient is screened but not enrolled in the study and is later screened again during a subsequent admission, the patient will receive a new unique PID, as they will each time they are screened for enrollment.

If a patient is determined ineligible for the study, a list of radio button choices will be displayed in PIWeb for “Reason(s) patient is ineligible”, where all known reasons for ineligibility should be selected. If "other reason ineligible" is selected, a text explanation (without carriage returns) should be entered into "explanation of ineligibility" describing the other reason. Screening and enrollment activities will end at this time for ineligible patients.

Informed Consent

Eligible patients will be informed about the study and consent procedures will be initiated. Before a patient can be enrolled in the study, the “Evaluation to Sign a Consent” must be completed. The study nurse will perform the evaluation of consentability with the patient using an online version of the Evaluation to Sign a Consent Form contained within PIWeb, and will log the patient’s responses into PIWeb. If the patient is deemed able to consent, then consent will be requested and the enrollment process will continue.

The site nurse will meet with the prospective participants and relevant family members to review the consent document(s) and/or provide an oral explanation of the study. As part of the consent process, individuals will be given the opportunity to ask questions and/or consult with family and/or friends before making a considered decision about whether or not to participate in the study. The patients should be given approximately one day to decide whether or not they would like to participate in the study.

Signed consent and HIPAA forms will be obtained from the patient or their legally authorized representative. Signed consent means research participants will be asked to sign and date a written consent form. A copy of the consent and HIPAA form will be placed in the study binder that will be sent home with the patient and, where required, another copy will be kept in patient’s medical record. As part of the consent process, we will inform the patient that if they provide us with a secondary contact, we will only contact this person at the phone number provided by the patient and only if we are unable to reach the patient after five attempts over three days. We will
also inform the patient that if we do contact the secondary contact, only the patient's name, that the patient is enrolled in our study, and that we have been unable to reach the patient in the specified time period will be disclosed.

The project directors at each site will keep all patients’ signed consent and HIPAA forms in the source document binder in a secure place (locked office, locked drawer). Scanned copies of the signed consent and HIPAA forms will be sent by encrypted email by project directors to the UCLA project director as PDF files on a weekly basis for back up purposes.

**Enrollment and PIWeb Fields**

Once consent is obtained, the patient is considered enrolled in the study and the study nurse will continue with the guided enrollment process using PIWeb, including:

- **New York Heart Association (NYHA) Stage.** NYHA classification at the time of admission is to be assessed by the study nurse as per the descriptions outlined in Appendix B.
- **Patient's best phone number.** This number is needed for all patients and not just for intervention patients, as this is the number that will be used for follow up survey calls.
- **Date of discharge.** Left blank at this time, to be entered later by the site project director when the patient is discharged from the hospital. **This date should never be changed** (unless entered in error, and in this case should be corrected by alerting the overall project director or study analyst who will make and document the change) as other dates and actions, such as call center calls and survey calls, are generated from and dependent upon this date.
- **Enrollment status.** Left blank at this time, to be entered later, and updated as needed, by the site project director when one of the statuses becomes relevant.
  - Discharged/Active in study – when the patient has been discharged from the initial hospitalization, discharged from a readmission, or returned to active status after being unavailable, for example, while traveling temporarily outside of the country.
  - Inactive in study – if the patient is inactive due to being discharged to a SNF, a hospital readmission, vacation, or unavailable to the study team for any reason.
  - Completed study – when the patient has completed the six month study enrollment period. This field will be updated by the survey team member who completes the final 180 day survey or abbreviated 180-day survey with the patient.
  - Expired – if the patient expires during the course of the six month enrollment period.
  - Full W/D – if the patient fully withdraws from all elements of the study, including that the patient does not want us to monitor their EMR. The UCLA project director will update this field in this case.
    - Any notes about the withdrawal should be entered in the Comments field at the bottom of the page
  - N/A
- **Status updated date.** Left blank at this time, to be entered later by the site project director whenever the patient’s Enrollment status changes.
  - This is the date that the patient’s status changes, not the date that the update is made in PIWeb. If, for example a patient expires but we are unsure of the date, the date that we find out about the status change should be entered here, with a note
in the Comments field, below on the same page in PIWeb, explaining the circumstances by which the status change was determined/discovered.
- This is the field where discharge date from any subsequent readmissions is recorded.
- This field will be overwritten each time it changes.

- **Completion date.** Automatically system-generated as discharge date plus 180 days as soon as the discharge date is entered into PIWeb
  - If a patient fully withdraws from the study or expires before the end of the enrollment period, the UCLA project director will manually update the study complete date to the date of the withdrawal or patient’s expiration date

- **Partial Participation level.** Left blank at this time, to be entered later by the overall project director if a patient later decides to opt out of the tele-monitoring equipment, the Call Center Nurse calls, and/or the survey calls. Patients are still considered partial participants if they opt out of all of the active elements of the study but will allow us to monitor their EMR and health system usage for the full six month enrollment period. For consistent reporting, for both intervention and control patients who opt out of all but EMR monitoring, all three “No” options should be checked. “Other” should be used for circumstances that don’t fit into those described above.

- **Details of Partial Participation.** Left blank at this time. Any relevant information such as who from the study team received the partial participation request and reason the request was made, if given, should be entered here.

- **Participation level updated.** Left blank at this time. The date that the patient requested partial participation.

Before randomization is performed, the study nurse will administer the online baseline survey and TIBI, and will be reminded to do so via a prompt in PIWeb. A paper copy of the baseline survey and/or the TIBI can be provided to patients to assist with completion if needed.

For patients being evaluated for PCI, the patient will be informed when approached that if a PCI is required, they will not be eligible for the study. If the patient is agreeable and consents to participate, enrollment activities will proceed up through survey and TIBI completion. Randomization, however, will only occur if PCI is not performed. If the patient is determined to require PCI, then the patient will be ineligible for the study.

Once the baseline survey and TIBI are completed, the patient will be randomly assigned to either the intervention group or the control group. Randomization is performed through PIWeb via a web-based computerized random number generator using permuted-block randomization with varying block sizes of 4, 6, and 8 by study site.

If a patient is enrolled in the study and at some point withdraws or is withdrawn from the study for any reason, he/she cannot be re-enrolled.

As soon as a patient is enrolled, it is best to continue moving forward with study activities to ensure that all pre-discharge activities are completed before the patient is discharged from the hospital. It may be helpful for the site nurse to check with the floor nurses or medical staff to find
out the patient’s anticipated discharge date.

To avoid skewing hospital provider (physician and nurse) perceptions of the control versus intervention patients, notes indicating study enrollment should not be placed in the patient’s medical record.

**Patients who are eligible but are discharged prior to being approached**
Answer “yes” to “Is patient eligible” and answer “no” to “Did patient consent?”. Then in the "Why did the patient not consent?" box, enter "discharged" as the first word in your comment. You can then add any additional notes.

**Patients who are eligible but refuse to participate**
Answer “yes” to “Is patient eligible” and answer “no” to “Did patient consent?”. Then in the "Why did the patient not consent?" box, enter "refused" as the first word in your comment. Any additional notes, including reasons for refusal can be entered after that.

**Patients who are eligible but physician does not wish for them to participate**
Answer “yes” to “Is patient eligible” and answer “no” to “Did patient consent?”. Then in the "Why did the patient not consent?" box, explain that the physician asked that the patient not be approached for participation. Any additional notes can be entered as well.

**Patients who decline participation but might be candidates upon subsequent admission**
Answer “yes” to “Is patient eligible” and answer “no” to “Did patient consent?”. Then in the "Why did the patient not consent?" box, enter "soft refusal". Any additional notes, including reasons for refusal can be entered after that.

**Randomization**
Once the baseline survey and TIBI are completed, the patient will be randomly assigned to either the intervention group or the control group using a web-based computerized random number generator in the Randomization section of PIWeb. The study nurse will exit the “Collect or Enter Data” section of PIWeb and go back to the PIWeb home screen to get to the “Randomization” section. On the randomization screen, the hospital site and patient’s PID are entered and the patient is randomly assigned to one of the two groups. The study nurse must then return to the “Collect or Enter Data” section to indicate that the patient was randomized and to which group, before proceeding with enrollment activities.
Trial Procedures: Post-Randomization Steps – Control Group

Patients assigned to the control group will receive the standard of care that is normally provided by the admitting hospital.

Please note:

- These patients will not receive calls from the Call Center Nurses, and no information about these patients will be sent to the call center.
- No letter will be sent to physicians whose patients are assigned to the control arm of the study.

Patients in the control arm will receive a control patient study binder to help remind them that they are participating in the study and that they will be contacted for telephone surveys at the following time intervals: 7-days, 28-days and 180-days after discharge.

Continuing enrollment procedures in PIWeb

The following information is captured on the “Communication: General Info” page of PIWeb:

- Patient name, age, MRN, date of discharge, preferred language, phone number, best time to reach the patient, secondary contact number, etc.
  - Special comments about the patient can be left by the study nurse for team members.
  - If possible, a secondary contact and his/her relationship to the patient is identified.
  - In the “If not English, preferred language” field – the language entered in this field will be used to guide interpreter service needs.
    - Note: If the patient has a family member who can speak English and communication through the family member is the preferred method of communication, then please indicate this in the notes or comments on the page.

In addition, physician name and contact information is captured on the final page of PIWeb, and the patient’s primary heart failure provider is indicated.

BEAT-HF Binder for Control Group Patients

Content of BEAT-HF Binder for Control Group Patients:

- Study summary
- Copy of the signed consent form
- Copy of the signed HIPAA agreement
- Survey call schedule
- Copy of the 7-day survey

If there is any site-specific educational material provided to patients as part of usual care at a site, the control group patients should receive it from their bedside nurses. If control group patients ask for further educational material, study nurses shall refer them to their bedside nurses.
**Trial Procedures: Post-Randomization Steps - Intervention Group**

Study nurses will communicate essential information about enrolled intervention patients through PIWeb as they go through the pre-discharge procedures. Call center nurses will have the ability to look into PIWeb daily, or as frequently as needed, to see all new subjects that have been enrolled and randomized into the intervention arm. Information that is reflected in PIWeb will make the hand-off process as efficient as possible, will help the call center nurse quickly know what education each patient has received and which topics should be reemphasized, and will avoid duplication of effort and manual entry of data.

**Continuing enrollment procedures in PIWeb**

The following information is captured on the “Communication: General Info” page of PIWeb:

- Patient name, age, MRN, date of discharge, preferred language, phone number, best time to reach the patient, secondary contact number, etc.
  - Special comments about the patient can be left by the study nurse for team members.
  - If possible, a secondary contact and his/her relationship to the patient is identified.
  - In the “If not English, preferred language” field – the language entered in this field will be used to guide interpreter service needs.
    - Note: If the patient has a family member who can speak English and communication through the family member is the preferred method of communication, then please indicate this in the notes or comments on the page.
- Barriers to care and learning. One of the responsibilities of the study nurse is to talk to patients to understand if there are any barriers to care. All applicable barriers to care should be indicated:
  - Language barrier
  - Emotional limitations
  - Physical limitations
  - Cognitive limitations
  - Financial
  - Lack of motivation
  - Cultural factors
  - Transportation barriers
  - Health literacy
  - Other
- Level of patient understanding for each of the eight teaching items and if a caregiver was present at the time of teaching. This section includes items relating to both heart failure and use of the study equipment. For the heart failure education items, the relevant pages in the UNC heart failure education booklet (provided in the intervention patient binder) are displayed and should be used for teaching. The following are the teaching items to be covered ahead of patient discharge, with more detailed descriptions provided in Appendix C of this manual:
  - HF basics -- diagnosis & recognizing symptoms
- Daily assessment
- HF medications
- Low-salt eating plan
- Fluid intake
- Physical activity
- Study process & equipment
- Follow-up care

The following information is captured on the final page of PIWeb

- Patient’s providers’ information
  - The Primary HF Provider selection will let the site project director know which provider should be sent the letter informing them that their patient has been enrolled in the intervention arm of the study.
    - Physician name and contact information, however, is entered for both intervention and control patients.
  - Ideal Life serial number for cell pod, BP manager, and scale; and whether the patient has taken the device from hospital or asked that the device be shipped.
    - If equipment is to be shipped to an alternate address, text entry boxes for the alternate address will be displayed after this option is selected.
    - **Cellular Adapter EDGE** was part of the first generation of study equipment and is no longer in use.

Intervention patients should still receive the standard of care that is provided by the bedside nurses, even though they will be receiving additional services from the study nurse.

**BEAT-HF Binder for Intervention Group Patients**

Every patient who gets enrolled in the study will receive a BEAT-HF binder, but the intervention patient binder has more content than the control patient binder. The intervention patient binder includes the UNC Heart Failure educational material and Ideal Life equipment instructions.

Content of BEAT-HF Binder for Intervention Group Patients:

- Study summary
- Copy of the signed consent form
- Copy of the signed HIPAA agreement
- Call center nurse names and photos
- Survey call schedule
- Copy of the 7-day survey
- UNC heart failure education materials
- Examples of self-management tools
- Ideal Life device information
  - Serial numbers of the patient’s IdealLife equipment
  - Equipment instructions
- Notes, such as:
Discharge date
Discharge weight
Follow-up appointment date
Doctor’s name and phone number
Questions for my doctor
Hospitalization History

- Because the Ideal Life equipment does not support the character set required for Russian or Persian, patients who speak these languages will receive a translation page in their binder that will associate each symptom question displayed on the BP manager in English with the written Russian or Persian translation on the binder page. Please note that for these patients, each question is preceded by a number in a bracket, e.g., "[1]", on the BP manager to help make question identification easier. **This process will need to be explained to the patient by the study nurse as part of the equipment training.**

**Identifying the Call Center Nurse for Each Patient**
In order to have a more personal handoff from the study nurse in the hospital to the call center nurse who will be managing the patient’s post-discharge care, each patient will be paired with a primary call center nurse based on the institution at which the patient was enrolled in the study. Each patient will be shown the page in their study binder with the name and photo of the call center nurse with whom they are paired, and told to expect their first call center follow up call within three days of discharge. The name and photo of other call center nurses will also be provided to each patient on the same binder page, as there will be occasions, e.g., trigger calls or days off, that a call center nurse other than the patient’s usual call center nurse may need to contact them.

**Unfinished Pre-Discharge Activity**
If there is an unexpected or premature discharge before the study nurse can complete the patient education activities, this should be documented by the study nurse in the **Notes** fields on the Communication pages in PIWeb. The call center nurses will then know if anything was not covered during the hospitalization, and can provide patients with additional education or information as needed (e.g., how to set up the Ideal-Life devices). However, we expect most patients to complete most of, and ideally all of, the education activities prior to discharge.

**Handling Emotional Distress and Suicide Risk**
The study nurse shall immediately inform hospital staff as well as the site principal investigator if he/she encounters a patient having suicidal thoughts.

**Letter to Primary Heart Failure Provider**
For intervention patients, the site project director will send a letter to the patient’s primary heart failure provider to let him/her know about the study and that a patient of his/hers has been enrolled in the intervention arm of the study. The letter will include a summary of the study and the default biometric monitoring parameters, and the provider is requested to let us know if he/she would like to modify the parameters for any given patient. The letter will also indicate the method by which we plan to contact the provider for urgent and for non-urgent matters, and will
also request that we be notified if a different method is preferred. Every site will use the project standard letter, but it will be sent from the local site PI’s email address.
Trial Procedures: Intervention Equipment

Connectivity
The equipment transmits best via cellular service. If cellular service is not available in an area, as determined using cell service coverage maps, then a landline or Ethernet can be considered. It is possible that cellular connectivity could be disrupted by other wireless devices in the patient’s home like multiple Bluetooth devices. Patients should be warned about the possible interference; and if this is an issue, one suggestion would be to have the patient turn off other wireless devices when they conduct their daily transmission.

Troubleshooting/Failure
In the event of equipment malfunction at the site prior to being sent home with a patient, the study nurse can contact Ideal Life at 1-800-611-2660 for troubleshooting assistance. It is helpful to have additional equipment available on hand. If equipment is determined to be malfunctioning, the equipment will be returned to Ideal Life.

Going Home
Prior to discharge, participants will be given the remote measurement devices (weight scale, and a BP manager to measure BP and heart rate and for answering symptoms questions), and the communication device (cell pod) to bring home. The serial numbers of the scale, BP manager/cuff, and cell pod given to the patient must be entered in the patient’s PIWeb record by the study nurse, and should also be recorded in the patient’s study binder. The call center nurse will use the serial numbers entered in PIWeb to set up their new patients for monitoring in the IdealLife portal. The serial numbers entered into PIWeb are also used to track equipment assignment and inventory.

Preferably each patient will take his/her equipment from the hospital to home at the time of discharge; some patients, however, might prefer to have the equipment mailed to their home. The study nurse should confirm preferred time and deliver address for delivery with the patient. If the equipment is to be shipped to an alternate address, Shipped to alternate address should be selected on the final page of PIWeb, and text boxes for Device shipping address will be displayed where the address for equipment shipment should be entered.

For patients whose equipment will be shipped from the UCLA study center, the study nurse will send an email to the UCLA project director and the patient’s call center nurse – and cc the other call center nurses – with the patient’s PID and when the devices should be shipped. Equipment should only be shipped once the discharge date is certain and the patient is discharged, or sooner ONLY if it has been confirmed that there will be someone at the address to receive the equipment. In addition, the study nurse should specify in the email the BP cuff size and type of scale that the patient will require. Devices will be sent by FedEx service to the requested shipping address from the UCLA study center, and the device serial numbers will be entered into PIWeb by a UCLA study team member.

Site Storage
We should strive to keep approximately 5-10 sets of devices at each site, depending upon anticipated enrollment volume at each site. Each site will determine the most convenient available
storage area for equipment inventory, which may be at the hospital or off-site at the local study office. Equipment should not be placed in extreme climates (too hot, too humid) or in direct sunlight or dust.

When the number of devices drops below 2-5, the site project director should be notified so that they can communicate back to the UCLA project director that more devices should be shipped from the UCLA study center to the local site. Equipment should be tested upon receipt to ensure they are working properly.

For UCLA and CSMC, equipment is “pre-bundled” (scale, BP manager, and cell pod) at the site and the serial numbers of the bundles are entered by a UCLA study team member in the Ideal Life portal with placeholder (“dummy”) patient identifiers in advance of being given to patients. The placeholder information is replaced with the actual patient information by the call center nurse once the equipment is assigned to a patient. This was done so that the study nurse could have the patient take a reading and at the same time make sure the devices transmit normally.

Isolation Patients
Some patients are in isolation. Please follow the below protocol to minimize risk of infection:

1. All equipment items should be cleansed with Clorox (or equivalent) wipes before leaving one patient’s room or hospital, regardless whether patient has been in isolation or not.
   a. Clearly identify and separate areas for clean and used equipment. Maintain storage area cleanliness.
   b. Equipment should be cleaned by wiping down with a cloth dampened with solution of water and mild detergent, or use mild antibacterial wipes. Glass cleaner can be used to clean smudges on plastic or glass surfaces.

2. For isolation patients, in order to minimize contact with items of equipment, consider using a cover where possible (e.g. baggie over scale) if the patient will not be taking the equipment home with them.

Non-English Speaking Patients
The study nurse will indicate in the If not English, preferred language field, the language that should be used for verbal communication with the patient as well as so that the BP manager is set up correctly and the symptoms questions are set up properly in the IdealLife portal. For Spanish language patients, the study nurse will set up both the scale and BP manager to indicate Spanish language instead of English. For patients who speak Persian or Russian, the equipment should be set for English.

For all non-English speaking patients, the call center nurse will use the preferred language field to know how to set up the patient’s message assignment in the IdealLife portal so that symptoms questions are displayed either in English, Spanish, or in English with numeric reference numbers in brackets. Message assignments in the IdealLife portal are as follows:

- For English – “ABC – English” and “DEF – English”
- For Spanish – “ABC – Spanish” and “DEF – Spanish”
- For Persian or Russian – “123-English” and “456-English”
Equipment Return

Study equipment will need to be returned to the UCLA study center either at the end of the six month study enrollment period, or prior to the end of the six months under some circumstances. The patient’s mailing address for the equipment return packaging should always be verified by the team member speaking with the patient about equipment return.

- At the end of six months, the call center nurse will let the patient know it is time to return the study equipment and that preaddressed packaging with pre-paid postage will be sent to them at this time. At the discretion of the call center nurse on the final phone call, the patient may be offered one of the two equipment return alternatives described below.
- For patients who choose to fully withdraw from the study or from the tele-monitoring portion of the study prior to the end of their six month study period, shipping materials will be sent to the patient as soon as we are made aware of the withdrawal. At the discretion of the team member notified of the withdrawal, the patient may be offered one of the two equipment return alternatives described below.
- For patients who expire during their six month study period, the patient's secondary contact will be contacted by the UCLA project director to determine the best mailing address and name for us to send the shipping materials to. At the discretion of the UCLA project director, the secondary contact may be offered one of the two equipment return alternatives described below.
- For patients who are no longer able to reach (i.e., provided phone numbers are no longer working or never answered), and from whom we would like to continue to try to receive back study equipment, a letter will be sent to the last known address we have for the patient, requesting the patient contact us either via telephone or using an enclosed, stamped and addressed envelope, to let us know how we can reach them.
- For patients who we are still able to reach, but who have for some reason not sent back the study equipment to us after receiving the prepaid return shipping materials, a UCLA study team member will follow up with a phone call 10 days after the materials return package has been delivered to the patient, and offer one of the two alternative means for equipment return described below.

Equipment return alternatives:

- For UCLA and CSMC patients local to the UCLA study center, a study team member can pick up the equipment from the patient’s home:
  - The UCLA project director should be informed via email of any local patients who would like to have their equipment picked up so that a UCLA study team member can call to make pick-up arrangements.
- For UCD patients, the patient can return the equipment at their next clinic visit:
  - The UCD project director should be informed of any patients who will be returning equipment at their next clinic visit so that these patients’ EMR can be monitored for the next scheduled visit, and a UCLA study team member will call the patient the day before their visit with a reminder to bring the equipment with them to their appointment.
  - This equipment can be returned to the UCD equipment inventory for reuse after following the steps outlined in the section of this manual describing procedures for...
preparing equipment for reuse

- The UCLA project director should be informed once equipment is received, so that the inventory tracking spreadsheet can be updated
Post-Discharge Surveys
Participants in both the control and intervention groups will be surveyed after discharge via phone calls by research staff. The post-discharge survey calls will occur at one week, at 28 days, and at 180 days. Patients will receive a $10 gift card for completing each of three telephone surveys, up to a total possible of $30 for completing all three telephone surveys. It is anticipated that one hour will be needed to complete each telephone survey.

A hard-copy of the 7-day survey will be sent home with the patient in the study binder, and a hard copy of each of the other two telephone surveys will be sent in advance of the next survey call to the patient’s home, in case the patient would like the opportunity to review the questions prior to the call. Patients may refuse to answer any questions that they do not want to answer and still remain in the study.

The gift cards and advance hard copies of each upcoming survey will be sent to the patient’s home address via FedEx by the survey team according to the following schedule:
- 7-day – the gift card and the 28 day survey are sent together with a thank you letter no later than one week after completing the 7-day survey
- 28-day – the gift card is sent with a thank you letter no later than one week after completing the 28-day survey. The 180-day survey is sent with a thank you letter 2-3 weeks ahead of the start of the 180-day survey calling window.
- 180-day survey – the gift card is sent with a thank you letter no later than one week after completing the survey.

Withdrawal of Participation
Patients may fully withdraw from the study by their own decision at any time without consequences of any kind. The investigator may withdraw a patient from participating in the research if circumstances arise which warrant doing so.

At any time after enrollment, the patient may also choose to only partially participate in study activities, for example, choosing to no longer answer telephone surveys. A patient will still be considered a partial participant if they withdraw from all active components of the study, but still allow us to track them via their EMR for the full six month study enrollment period. We would like for patients to remain on the full protocol and complete the surveys, but understand that this may not be possible in some cases and will accommodate all full withdrawals and partial participation requests.

Whoever is informed of the patient’s partial withdrawal or full withdrawal from the study should send an email to the UCLA project director so that the patient’s status can be updated in PIWeb.

End of Trial
The total time of study for each participant is 180 days from discharge. Patients will be informed of the end of the study when they receive their 180-day survey call.
Trial Procedures: Post-Discharge Activities – Intervention Group

Remote Monitoring
Following discharge, patients will be asked to transmit automated biometric information and symptoms daily to the centralized call center using the measurement equipment and the communication device. As soon as the patient’s BP manager is switched on, the patient will be prompted to respond to a series of symptom questions related to their heart failure status and general health, and then BP and heart rate can be measured using the BP cuff. One of two alternating sets of three questions will be asked of the patient each day via the BP monitor. When the patient steps on the scale, the scale will turn on and the patient’s weight will be captured.

Information from the remote monitoring system will be automatically downloaded to the IdealLife secure server for review by the call center nurses. Individuals whose symptoms or biometric parameters are out of the established range (such as a weight gain of greater than 3 pounds in one day or 5 pounds in one week) will be flagged.

Call Center
A call center nurse will contact the intervention patients within three days of discharge to reinforce patient education, medication, and follow-up plans, and to conduct problem-solving if necessary. The call center nurses have access to PIWeb, which includes the randomization screen where they can check daily, or more frequently, to see if any intervention patients from the institution(s) they are responsible for have been enrolled in the study. Once the call center nurse has identified a new patient enrolled, it is the responsibility of the call center nurse to periodically check the patient’s EMR for discharge to know when to make the first call. Call center nurses have access to EMR systems at most sites; in the case where EMR access was unable to be granted, the local site project director or local study nurse is responsible for letting the call center nurses know as soon as a newly enrolled patient has been discharged.

Call center nurses will also conduct trigger calls, scheduled weekly calls during the first month, and scheduled monthly calls during the subsequent five months. The call center nurses should function as a medical coach, where it makes sense for them to advise and/or make clinical decisions, and not as a pass-through. Calls might be recorded for quality assurance purposes. The call center will operate also during weekends and holidays, but generally only for responding to trigger calls or, if unavoidable, a scheduled outbound call.

The goal of these calls is not to replace routine management, but to facilitate management. We want to empower intervention arm patients to be proactive in calling their provider when they need to, and for the call center nurse to provide necessary information back to the primary heart failure provider. For example, it is not call center nurses’ responsibility to schedule office appointments for subjects. Instead, patients would be encouraged to contact their physician directly and make the appointment themselves (e.g., if needed, coaching patients on what to say when calling the physician’s office). Patients are encouraged to contact their regular care source when needed. Call center nurses could contact other study staff at the patient’s enrollment site when having difficulty in contacting provider.
If the call center nurse is unable to reach a patient for any of the follow-up calls, the call center nurse can try to contact the patient up to three times in one day. If the patient cannot be reached after five phone calls at various times in three days, the secondary contact will be called to inquire about the patient’s condition.

**Patients discharged to a Skilled Nursing Facility (SNF)**
When a patient is discharged to a SNF, the call center nurse will call the SNF on a weekly basis to see if the patient has been discharged or when the patient will be discharged. Some SNFs will share this information and others will not. In the case where the SNFs don’t share this information, the call center nurse will call the home number or the secondary contact number on a weekly basis instead.

**First Follow-up Call**
The goal is that first call be placed in the first three days after discharge. We are allowing a three day window before or after the third day after discharge. If the first call happens in the second week, (day 8 through 14), it would be considered the second call out of the four weekly calls rather than as the first call, and the first call will be recorded as skipped. We will try to minimize stacking post-discharge calls (standard site calls, which vary from site to site; call center calls; and survey calls). The expected duration of first call will be approximately 45 minutes in length.

During the first follow-up call the call center nurse will assess any potential problems with care transitions. Any identified issues, medication or otherwise, will be relayed to the primary heart failure provider, or if different, the primary care provider or provider who will first see the patient following contact. If the patient is having trouble scheduling timely outpatient care, the call center nurses will work with the patient to solve how to set an appointment with the outpatient primary heart failure provider.

It is recommended to evolve the relationship by asking questions like "is there anything about your health we can help you with today?" Such questions will help demonstrate to the patient that the call focuses on their agenda. Patients should also be asked what is the best day and time to reach them for next calls. This gives patients a sense of empowerment and establishes some sort of buy in for them. Patients are more available when asked for this information.

The following checklist would be used during the first call:
- Review/Reinforce patient education
- Review follow up plans (CCNs will have the ability to tap into EMRs to see if follow-up plans like appointments may have occurred)
- Review specific medications within classes that are important treatments for heart failure (including not using COX-2 inhibitors); call center nurses will ask patients to bring their medications to the telephone to review them and address medication-related problems.
- Review/Reinforce troubleshooting plans (e.g., who should be contacted and under what circumstances)
- Troubleshooting heart failure and non-heart failure issues, especially heart failure issues.
- Make sure patients are adhering to their treatment plans.
• Attend to problems or potential problems as efficiently as possible.
• Reinforce the use of the remote monitoring technology.

If a patient asks a question that call study nurses do not know the answer, they should encourage the patient to call his/her provider. The nurses are discouraged from calling the provider to help the patient with his/her question.

**Weekly calls**
Patients will subsequently be called on a weekly basis for a total of at least four telephone contacts during the first 30 days of the enrollment period. However, call center nurses may increase the total number of calls during the 30 day period as deemed necessary, in addition to responding to trigger calls.

The four weekly calls are roughly similar in terms of discussions, but the emphasis would be on those issues where the patient needs more education and guidance. It is estimated that the duration of each weekly call will be around 30 minutes in length, but will be dependent on the course of patient’s conversation with the call center nurse.

The following checklist would be used in weekly calls:
• Review/Reinforce patient education
• Review follow up plans
• Review/Reinforce troubleshooting plans
• Troubleshooting heart failure and non-heart failure issues, especially heart failure issues.
• Make sure patients are adhering to the intervention.
• Make attention to problems or potential problems as efficiently a possible.
• Reinforce the use of the Ideal Life technology.

**Monthly calls**
After the 30-day period, call center nurses will contact the patients on a monthly basis for the remainder of the six month enrollment period. These monthly calls will not be as intensive (e.g., will not explicitly go through each medication as described earlier) as the calls during the first 30 days, but will be problem-oriented and will provide guidance on any heart failure management issues raised by the patient and/or caregivers. Reinforcing the use of the IdealLife technology should be an element of each call.

**Call Windows**
Realizing it may not be possible to reach a patient exactly on the specified call period date, we have established windows for making each call:
• First follow up call – plus or minus 3 days from three days post-discharge
• Weekly calls -- there are a total of three scheduled weekly calls
  o discharge date + 8 < 2nd call < discharge date + 14
  o discharge date + 15 < 3rd call < discharge date + 21
  o discharge date + 22 < 4th call < discharge date + 28
• Monthly calls – there are a total of five scheduled monthly calls, with the first call occurring
60 days after discharge. The window for monthly calls is plus or minus 7 days from the scheduled call date.

- Final call – plus or minus 7 days from the 180 day mark

**Inbound Calls**

The call center is set up as an outbound only call center. While the call center nurses are all located at our centralized call center at UCLA, calls made to patients enrolled at any given site will be made on a phone line that is programmed to display a local area code phone number for that patient’s institution (e.g., 415 for patients enrolled at UCSF). Each phone number will correspond to a voice mailbox located at each of the sites. This voice mailbox will be in place at each site for patients who capture the call center phone number using caller id and who call back to leave messages; however, the outgoing message on these voice mailboxes will inform the patients that these mailboxes are checked on an infrequent basis (at most once daily and on weekdays only). The local voice mailbox will be checked periodically by the local site project director, and the site project director will send an email to the call center nurses so that they can determine if the call should be returned. If the call is returned, it will be documented similarly to any other trigger call.

**Non-English Speaking Patients**

For non-English speaking patients, if the site nurse does not speak the patient’s language, the site should use the contracted interpreter service.

Similarly, the call center nurses can place calls through a third party on TDD line to communicate with patients who have hearing or speaking problems. TDD allows such patients to read the conversation on a small monitor of their specific telephone gadget and reply back by typing instead of speaking.

**Parameters and Trigger Alerts Protocols**

Call center nurses have an important role in observing the results of daily measurements and taking necessary actions if they encounter a trigger alert, or when they determine that a patient has become symptomatic. There is a set of default thresholds for various biometric parameters that could trigger an alert, and potentially a call to the primary heart failure provider. Primary heart failure providers are informed of the default parameters and are given the opportunity to change them up front by contacting the site project director, whose name and contact information is provided in the letter sent to physicians upon enrollment of one of their patients in the intervention group.

The table below depicts the parameters that will prompt a call from the call center to the patient:

<table>
<thead>
<tr>
<th>Biometric Parameter</th>
<th>Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBP</td>
<td>SBP &lt; 90 mmHG</td>
</tr>
<tr>
<td></td>
<td>SBP &gt; 160 mmHG</td>
</tr>
<tr>
<td>Heart Rate</td>
<td>HR &lt; 50</td>
</tr>
<tr>
<td></td>
<td>HR &gt; 100</td>
</tr>
<tr>
<td>Weight</td>
<td>Daily gain &gt; 3 Pounds</td>
</tr>
<tr>
<td></td>
<td>Weekly gain &gt; 5 Pounds</td>
</tr>
</tbody>
</table>
The table below depicts the parameters that will prompt a call from the call center to the patient as well as to the primary heart failure provider:

<table>
<thead>
<tr>
<th>Biometric Parameter</th>
<th>Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>SBP w/ Symptoms</td>
<td>SBP &lt; 90 mmHG</td>
</tr>
<tr>
<td>SBP w/o Symptoms</td>
<td>SBP &lt; 80 mmHG</td>
</tr>
<tr>
<td>Heart Rate w/ Symptoms</td>
<td>HR &lt; 50</td>
</tr>
<tr>
<td>Heart Rate w/o Symptoms</td>
<td>HR &lt; 40</td>
</tr>
<tr>
<td>Weight w/ Symptoms</td>
<td>Daily gain &gt; 3 Pounds</td>
</tr>
</tbody>
</table>

These thresholds can be changed for a particular patient at the discretion of the primary heart failure provider. Initially after a patient’s discharge, since call center nurses are not familiar with the patient’s health condition, they will call the patient to assess each trigger alert. For some patients, for example patients who have arrhythmias like atrial fibrillation and whose pulse is almost always reported above 100, the nurses should use their discretion regarding calling on every trigger of a certain type/level once they become very familiar with a patient and the patient’s condition. Talking to patient over the phone, the nurse will assess the patient’s condition and decide whether they should recommend that the patient call their primary heart failure provider, the nurse should call the primary heart failure provider, initiate a 911 call, and/or make some other recommendations to the patient.

There are also some general and specific symptom questions that each patient will answer every day prior to performing the above-mentioned tests. These symptom questions help the nurses to evaluate the general condition as well as the heart performance of the patient, and may trigger a call to the primary heart failure provider if biometric thresholds are met. Each day, the patient will be asked to respond to an alternating subset of three questions:

<table>
<thead>
<tr>
<th>Question</th>
<th>Trigger</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you felt more short of breath in the last day?</td>
<td>Yes</td>
</tr>
<tr>
<td>Have you noticed more swelling in the last day?</td>
<td>Yes</td>
</tr>
<tr>
<td>Did you wake up more short of breath last night?</td>
<td>Yes</td>
</tr>
<tr>
<td>Did you sleep in a chair, or propped up on pillows, more than usual last night?</td>
<td>Yes</td>
</tr>
<tr>
<td>Have you had any light-headedness or dizziness in the last day?</td>
<td>Yes</td>
</tr>
<tr>
<td>Today, would you say your health is excellent, very good, good, fair, or poor?</td>
<td>Poor</td>
</tr>
<tr>
<td>Compared to yesterday, would you say you are feeling about the same, better, worse, or much worse?</td>
<td>Much worse</td>
</tr>
</tbody>
</table>

As with the biometric parameters, the call center nurses will call the patient to assess and verify the condition. If they find the patient is symptomatic they will contact the primary heart failure provider to let him/her know.

Depending on patient’s symptoms and level of exacerbation, the call center nurse may call 911 and advise patient to go to the ER as soon as possible. In less severe conditions but still urgent, the
A nurse may contact the patient’s physician through pager or phone. In non-emergent situations, the physician may be notified through email or other means on a non-urgent basis. In sites that have installed EPIC EMR system, physicians can be quickly notified through the EPIC messages system.

<table>
<thead>
<tr>
<th>Situation</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-urgent condition</td>
<td>Non-urgent physician notification</td>
</tr>
<tr>
<td>Urgent condition</td>
<td>Urgent physician notification by pager/call</td>
</tr>
<tr>
<td>Emergent condition</td>
<td>Call 911</td>
</tr>
</tbody>
</table>

Since the Call Center Nurses would have access to each patient’s EMR, they can look into recent hospitalization records and get a sense of whether the readings are something that should be expected or not.

Some examples of emergent and urgent conditions in the below table:

<table>
<thead>
<tr>
<th>Examples of Emergent Condition</th>
<th>Examples of Urgent Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Irregular or rapid pulse</td>
<td>• Difficulty in sleeping</td>
</tr>
<tr>
<td>• Increased dyspnea</td>
<td>• Increased swelling in ankle</td>
</tr>
<tr>
<td>• Dyspnea while seated</td>
<td>• Increased weakness or fatigue</td>
</tr>
<tr>
<td>• Extreme sweating</td>
<td>• Frequently dry cough</td>
</tr>
<tr>
<td>• Chest pain or chest pressure</td>
<td>• Increased wheezing</td>
</tr>
<tr>
<td>• Change in mental status</td>
<td>• Weight gain &gt; 3 pounds a day</td>
</tr>
<tr>
<td>• Blue lips, tongue, or fingernail beds</td>
<td>• Weight gain &gt; 5 pounds a week</td>
</tr>
<tr>
<td>• Inability to speak due to dyspnea</td>
<td>• Loss of appetite, indigestion</td>
</tr>
<tr>
<td>• Extreme fatigue</td>
<td>• Light headedness/dizziness</td>
</tr>
<tr>
<td>• Frothy pink or copious white sputum</td>
<td>• Upper respiratory infection with fever and cough</td>
</tr>
<tr>
<td>• Feeling of suffocation</td>
<td>• One time ICD shock without symptoms</td>
</tr>
<tr>
<td>• Sudden increase swelling in legs, feet, or abdomen</td>
<td></td>
</tr>
</tbody>
</table>
• ICD fired one time. Whenever a patient reports to the call center nurse that their ICD device fired once
  o If patient is asymptomatic:
    ▪ The call center nurse should instruct the patient to contact their ICD Clinic or primary heart failure provider as soon as possible to discuss the shock event and arrange appropriate follow-up
    ▪ The call center nurse should contact their ICD Clinic or primary heart failure provider concerning the report of ICD shock and relay information about patient's current status & instructions given to patient to call ICD clinic/provider.
  o If patient reports symptoms, i.e., chest pain, pressure, shortness of breath, abnormal heart beat, dizzy, confused or not feeling well
    ▪ The call center nurse should caution the patient not to attempt to drive himself/herself to the ED
    ▪ Based on patient's symptoms, the call center nurse should advise the patient to either have someone drive him/her immediately to the nearest ED or call "911"
    ▪ The call center nurse should contact primary heart failure provider and ICD Clinic concerning events and patient disposition

• ICD device fired two or more times
  o The call center nurse should advise the patient to have someone drive him/her immediately to the nearest ED or call "911"

Making changes to biometric parameters
Whenever the call center nurse calls the primary heart failure provider, she would discuss the trigger alert and could ask whether the provider would like to set a new threshold or thresholds based on patient’s specific conditions. In addition, the letter sent to the primary heart failure provider upon patient enrollment includes a list of the standard parameters along with contact information for the local site project director and requests that if the physician would like to change the parameters for his/her patient, the physician should let us know. The call center nurse will make changes to a patient’s biometric parameters in the IdealLife portal only when changes are requested by the patient’s physician.

If primary the heart failure provider decides to adjust his/her own desired triggers based on patient’s condition or in response to the initial letter, the call center nurse or site project director will let Dr. Ong (and the call center nurse, if the change notice is received by the site project director) know by email. Changes will be effective immediately. Individualizing the parameters will minimize unnecessary alerts and trigger phone calls.

Primary heart failure Provider Unresponsive to Calls and Messages
In case the primary heart failure provider is unreachable by any means the call center nurses can ask the local site PI to help them reach the primary heart failure provider. Many physicians’ contact information like pagers, backline office phone numbers, and email addresses are available
through the EMR system of each site, and electronic lists have been put together for the sites where this information is not available online.

Missed Patient Readings
The call center nurses meet weekly with the UCLA study team member responsible for liaising with Ideal Life regarding compliance and device issues to review the possible causes of missed readings and what corrective action can be taken.

Readmission Notification
If a patient who is already on the trial gets hospitalized, daily readings would cease, which is a trigger for call center nurses to call patient to inquire the reason of stopping daily results. If call center nurses get notified of a patient's hospitalization, they will document it in their records and fill out an adverse event (AE) form and submit it to the UCLA study team member responsible for AE tracking.

Equipment Failure
In case of failure of the Ideal Life devices, patients should contact the Ideal Life toll free customer service line directly for assistance. Customer service is available Monday through Friday, 6am to 5pm PST. Sometimes patients will leave a message on the study voicemail or for Dr. Ong or for the site PI, and these calls will be returned by the call center nurses. If the call center nurse is unable to troubleshoot the equipment problem, then the call center nurse will alert Ideal Life of the issue and someone from Ideal Life will get in touch with the patient.

Transfer Call to EMS in Emergent Situations
In an emergent situation when the patient is alone, the call center nurse should remain on the line until the patient is able to speak directly with EMS personnel. When CCN transfers the patient's call directly to EMS dispatcher, the CCN will immediately provide the address where the patient is physically located as well as the patient's phone number. CCN will then confirm the EMS dispatcher does not need any further information from the CCN before disconnecting from the call. CCN will immediately notify the patient's primary heart failure provider and the overall Principal Investigator (Dr. Ong).

Handling Emotional Distress and Suicide Risk
The call center nurse, or any study team member, shall immediately notify the overall Principal Investigator (Dr. Ong) by pager and/or phone if he/she encounters a patient having suicidal thoughts and he/she should also contact the National Suicide Hotlines at 800-784-2433, 800-273-8255, or 800-799-4889 (Deaf Hotline).

Patient Abuse Issues
If the call center nurse, or any study team member, comes across a case of patient abuse he/she should contact the primary care provider to inform him/her about the situation. It can be difficult to verify the validity of an abuse claim based on a telephone call. Based on their discretion, the nurses may also need to call adult protective services. The overall Principal Investigator (Dr. Ong) will also be notified of all such situations.
Post-Discharge Surveys
Participants in both the control and intervention groups will be surveyed after discharge via phone calls by research staff. The post-discharge survey calls will occur at one week, at 28 days, and at 180 days. Patients will receive a $10 gift card for completing each of three telephone surveys, up to a total possible of $30 for completing all three telephone surveys. It is anticipated that one hour will be needed to complete each telephone survey.

A hard-copy of the 7-day survey will be sent home with the patient in the study binder, and a hard copy of each of the other two telephone surveys will be sent in advance of the next survey call to the patient’s home, in case the patient would like the opportunity to review the questions prior to the call. Patients may refuse to answer any questions that they do not want to answer and still remain in the study.

The gift cards and advance hard copies of each upcoming survey will be sent to the patient’s home address via FedEx by the survey team according to the following schedule:
- 7-day – the gift card and the 28 day survey are sent together with a thank you letter no later than one week after completing the 7-day survey
- 28-day – the gift card is sent with a thank you letter no later than one week after completing the 28-day survey. The 180-day survey is sent with a thank you letter 2-3 weeks ahead of the start of the 180-day survey calling window.
- 180-day survey – the gift card is sent with a thank you letter no later than one week after completing the survey.

Withdrawal of Participation
Patients may fully withdraw from the study by their own decision at any time without consequences of any kind. The investigator may withdraw a patient from participating in the research if circumstances arise which warrant doing so.

At any time after enrollment, the patient may also choose to only partially participate in study activities, for example, choosing to discontinue use of the tele-monitoring equipment. A patient will need to be withdrawn from the tele-monitoring and nurse call portions of the intervention if he/she moves out of state for the duration of the enrollment period, as California nursing licenses prohibit the nurses from practicing across state lines; but he/she will still be allowed to complete the telephone follow up surveys. A patient will still be considered a partial participant if they withdraw from all active components of the study, but still allow us to track them via their EMR for the full six month study enrollment period. We would like for patients to remain on the full protocol and complete the surveys, but understand that this may not be possible in some cases and will accommodate all full withdrawals and partial participation requests.

Whoever is informed of the patient’s partial withdrawal or full withdrawal from the study should send an email to the UCLA project director so that the patient’s status can be updated in PIWeb. In addition:
- an equipment return package will be sent to the patient for patients withdrawing from the tele-monitoring portion of the study
• on a case by case basis, the call center nurse may choose to confirm the withdrawal with the patient

**End of Trial**
The total time of study for each participant is 180 days from discharge. During the final call from the call center nurse, intervention patients will be asked to return the devices to the UCLA study center, using pre-paid shipping materials that will be sent to them; or via one of the other options described in the Equipment Return section of this guide. The call center nurse will send an email to the UCLA project director that the patient has completed the study and that either:

• an equipment return package should be sent
• an at-home equipment pick-up request was made (for some UCLA and CSMC patients local to the UCLA study center)
• the patient will return the devices at their next clinic visit (for some of Dr Tong’s UCD patients)

Upon return to the UCLA study center, all devices will be prepared for reuse and returned to inventory for use by subsequently enrolled patients.
Trial Procedures: Follow-up Telephone Surveys

Each day, the designated survey team member checks PIWeb for newly enrolled patients. These patients’ records are checked daily in PIWeb for discharge date, so that when a patient is discharged, a row is created for them at the bottom of the call log spreadsheet and their call window is highlighted to alert the team to a new participant with an open call window. All calls and call attempts for each study participant – including call date and time, outcome, and the caller’s initials – will be logged in this row that is established for each patient upon discharge. Once a survey has been completed, the completed call window in un-highlighted and the date the survey was completed is highlighted, indicating that a gift card needs to be sent to the patient. If the window for a given survey closes before the patient is reached, the closed call window is un-highlighted and “out of window” is entered into the survey completion date cell. Every day the survey team members scan the list for any newly opened call windows and any new, upcoming call windows are highlighted.

A current status field is maintained in the call log spreadsheet, containing up to date patient information from emails such as AE forms. For example, recent hospitalizations or hospice stays are noted here, indicating the patient is temporarily inactive in the study, the Enrollment Status field in PIWeb will be checked regularly to see when the patient is discharged or returned to active status.

If a patient is not reachable after a few calls or the numbers listed are not working, the survey team member will double check against PIWeb and/or, in the case of an intervention patient, ask the call center nurse if they’ve had any luck contacting the patient. If no information turns up, the local site project manager or local study nurse should be emailed for possible alternative contact information.

If a patient is unable to complete the survey
If the survey is only partially completed during a phone call, the survey team member will try to schedule another time that’s convenient for the patient to complete it. If the survey is only partially completed and patient is not interested in finishing, the remaining questions are marked as “refuse”.

Contacting secondary contacts
If the survey team member is unable to reach a patient after two call attempts for a given survey, the secondary contact(s) will be called.

Survey call windows
Each survey is scheduled to be performed for a specified time period, with an allowable call window established for each:
- 7-days survey – at 8 days plus or minus 4 days (day 4-12)
- 28-days survey – at 28 days plus or minus 7 days (day 21-35)
- 180-days survey – at 180 days plus 28 days (day 180-208)

180-day survey call
Once the patient has completed the 180-day survey or the abbreviated 180-day survey, the
patient’s Enrollment Status should be updated to “completed” in PIWeb, and an email should be sent to the UCLA study team member responsible for equipment tracking, so that the patient’s PID can be entered into the Equipment Return Tracking Spreadsheet and we know this patient’s equipment will need to be returned soon.

If during the course of the final survey call, the patient asks what to do with the equipment, the patient should be informed that we will send them a box and the patient’s address should be confirmed for shipping. An email should be sent to the call center nurses and the UCLA project director, so that the call center nurses are aware that equipment return was discussed, and so that an equipment return package can be sent to the patient.

**Abbreviated 180-day survey**
The abbreviated survey will be offered to patients who are reached during the 180 day contact window, but who indicate they do not want to complete the full 180 day survey when contacted. For patients who are not reached during the four week contact window for the 180 day survey, additional attempts to contact them may be made in order to complete an abbreviated 180 day survey.

**Mailing of gift cards and hard copies of upcoming surveys**
Gift cards and advance hard copies of each upcoming survey will be sent to the patient’s home address via FedEx by the survey team according to the following schedule:

- **7-day** – the gift card and the 28 day survey are sent together with a thank you letter no later than one week after completing the 7-day survey. A hard copy of the 7-day survey is included in the study binder that is sent home from the hospital with the patient.
- **28-day** – the gift card is sent with a thank you letter no later than one week after completing the 28-day survey. The 180-day survey is sent with a thank you letter 2-3 weeks ahead of the start of the 180-day survey calling window.
- **180-day survey** – the gift card is sent with a thank you letter no later than one week after completing the survey.

Patients who partially complete any given telephone survey will still receive a gift card for that survey. Patients who complete the abbreviated 180-day survey will also receive the $10 gift card.

Up to $5000.00 in gift cards may be kept on hand in the UCLA project office. To order additional gift cards, PSC and OHRPP have collaborated to make the availability of funding (cash/gift cards) more efficient. The PSC office now has Target and Ralphs gift cards in inventory so they can supply those cards as quickly as they supply cash.

**Gift card tracking**
The serial numbers of all gift cards stored in the UCLA study office and used for the study participants is kept in a spreadsheet on the local hard drive of the survey team member responsible for tracking and mailing gift cards and maintaining appropriate inventory level. The serial numbers are entered into the spreadsheet as soon as they are received at the UCLA study office. The gift cards are stored in a locked safe in the locked office of the responsible team member. As each gift card is mailed to a patient, the date that each gift card is sent is entered into
the call log spreadsheet, and a copy of the fedex airbill is stored along with a copy of the letter that was sent to the study participant.

We strive to maintain a minimum gift card inventory level of three weeks of cards on hand at any time. This is the number of cards we anticipate mailing in a three week period, although the number will vary throughout the course of the study.

Patients discharged to a Skilled Nursing Facility (SNF)
When a patient is discharged to a SNF, the survey team member will try to reach the patient in the SNF unless asked not to call the patient there. SNF numbers and bedroom numbers can often be found in the Comments field in PIWeb.

Patients requesting withdrawal from the study
If the patient says they no longer want to participate in the study, to the extent possible, please clarify what the patient means as they may mean they no longer want to answer survey calls, or no longer use the equipment, or they may want to withdraw altogether from the study. Please be sure to ask if they would be comfortable with passively participating in the study for the remainder of the study enrollment period (you can let them know the date) by allowing us to track their health system usage via their EMR and with no further contact from the study team.

Then let the UCLA project director know via an email that the patient would like to withdraw and the details of the level of withdrawal (i.e., full, or partial). If the patient seems angry or adamant about not wanting any more contact with anyone from the study, please include that in your email. In the case of an intervention patient withdrawal, the call center nurses should be made aware of this as they might choose to contact the patient to confirm the withdrawal if they feel they have an established relationship with the patient.

Handling Emotional Distress and Suicide Risk
The survey team, or any study team member, shall immediately notify the overall Principal Investigator (Dr. Ong) by pager and/or phone if he/she encounters a patient having suicidal thoughts and he/she should also contact the National Suicide Hotlines at 800-784-2433, 800-273-8255, or 800-799-4889 (Deaf Hotline).

Patient Abuse Issues
If the survey team member, or any study team member, comes across a case of patient abuse he/she should contact the primary care provider to inform him/her about the situation. It can be difficult to verify the validity of an abuse claim based on a telephone call. Based on their discretion, the nurses may also need to call adult protective services. The overall Principal Investigator (Dr. Ong) will also be notified of all such situations.

If a patient exhibits inappropriate behavior
If the patient is an intervention patient, the survey team member will check with the patient’s call center nurse to see if they’re having a similar experience. For both intervention and control patients, the incident is documented in the call log and the UCLA project director and PI are notified of the situation.
Monitoring patients for discharge
The local site project director is responsible for monitoring all patients enrolled at their site for discharge. The local site project director will check the randomization page in PIWeb on a daily basis for newly enrolled patients (both control and intervention) at their site. The local site project director will track on a daily basis the status of these patients for discharge or expiration, and will update *Enrollment Status* in PIWeb as soon as it changes. Timely updating of the *Enrollment Status* field, and more importantly *Discharge Date*, in PIWeb is crucial to the timeline of the study, as the survey team members will use this date to begin the survey call timeline. In addition, the enrollment period begins on the date the patient is discharged, NOT on the date the patient is enrolled in the study; and the *Completion Date* in PIWeb is automatically generated from this date once it is entered.

Letter to primary heart failure provider
The local site project director will check the randomization page in PIWeb on a daily basis for intervention patients enrolled at their site so that they can begin monitoring these patients for discharge. As soon as a patient is discharged, the site project director will update PIWeb with the patient’s discharge date and enrollment status, and send a letter to the patient’s physician. It is important that the discharge date be entered as soon as possible, as the survey team uses this date to schedule the survey calls, the first of which will occur a week post discharge.

The standard letter sent to the patient’s primary heart failure provider (typically the patient’s cardiologist, although the selection on the final page of PIWeb should be checked for conformation) informs the physician about the study and that a patient of theirs has been enrolled in the intervention arm. A summary of the study and the default biometric monitoring parameters is included in the letter and the provider is requested to let us know if he/she would like to modify the parameters for any given patient. The letter will also indicate the method by which we plan to contact the provider for urgent and for non-urgent matters, and will also request that we be notified if a different method is preferred. Every site will use the project standard letter, but it will be sent from the local site principal investigator’s email address.

Adverse Event (AE) tracking
The local site project directors are responsible for tracking patient readmissions and expirations that occur at their site, through daily enrollment screening and through daily checking of patient records for patients enrolled at their site. In addition, call center nurses will often learn of an adverse event through their tracking of and contact with the intervention patients; and the survey team members may also learn of adverse events when they make the survey calls to both intervention and control patients.

Whoever learns of the AE will fill out an AE form and email it to the UCLA study team member responsible for AE tracking. This UCLA team member will save a copy of the AE form on the I-drive, enter the event into the AE Summary Spreadsheet on the I-drive, and email the appropriate team members (survey team members, call center nurses for intervention patients, local site project director, and Dr Ong) to let them know of the AE. The local site project director will update the
patient’s Enrollment Status in PIWeb. At a minimum, an email should be sent to the UCLA team member as soon as an AE is detected so that other team members can be alerted to the event; and the form can be sent as soon as there is time to fill it out.

The local site project director at the readmission site (most of the time the same as the enrollment site, except sometimes there is crossover in the case of CSMC and UCLA) is responsible for monitoring the patient for discharge from a readmission and updating the patient’s Enrollment Status in PIWeb upon discharge (or expiration).

Checking project voice mail
The site project director will check the local project voicemail, a voicemail box set up to receive messages from patients who thought to capture the outbound call center nurse phone number using caller id. The project voicemail at each site should use the same standard outgoing message: "Hello. You have reached the voicemail box for the UC-[site-name] (or CSMC) study, BEAT-HF. If you need immediate assistance, please contact your physician or call 911. If you are trying to reach one of our call center nurses, please leave your name, phone number, and a message and a nurse will contact you. Please note that this voice mailbox is only checked periodically. Thank you”. The site project director should check the project voicemail every day or at least every other day (except weekends), and email any patient messages to the patient’s call center nurse and cc the other call center nurses.

Equipment return packages
Within a week of receiving notification that a patient (or secondary contact) is expecting an equipment return package, the package should be shipped out using FedEx ground. We should be particularly sensitive to the shipping timeframe for secondary contacts of patients who have expired, and try to send out the box within a few days at the most.

Most requests for equipment return mailings will come from the call center nurses, who will be discussing equipment return during the 180 day phone call. Once the request is received, the patient’s PID is entered into the Equipment Return spreadsheet on the I-drive along with the date that the send request was received. As soon as the box is sent, the shipment date is entered into this spreadsheet. As soon as the equipment is received back at the UCLA study center, the date the package was returned is entered into this spreadsheet. If the equipment is not received back at the UCLA study office within 10 days after the package was shipped to the patient, a follow up phone call will be made to the patient to ensure the package was received and to remind them to return the equipment. These calls will be tracked in the notes column of the spreadsheet.

Equipment that we cannot reasonably expect to have returned to us for any number of reasons, including inability to reach a patient or the patient lost the equipment, should be marked in red on the Equipment Return spreadsheet so that we know to know longer pursue return of that set of equipment. Patients who are allowed to continue using the equipment beyond the 180 day mark are highlighted in green on the spreadsheet so that we know to temporarily not pursue return of that set of equipment.

To help ensure we don’t miss out on any equipment returns, the survey team member completing
the 180 day survey will send an email to the UCLA project director so that the patient’s PID can be entered into the Equipment Return spreadsheet. The patient’s PID will be entered into the spreadsheet and a note will be entered in the notes column of the spreadsheet indicating that the 180-day survey has been completed; but a box will NOT be sent to these patients until either the call center nurse let’s us know to send a package, or if the patient asked about equipment return on the 180-day call and is now expecting a box.

Preparing equipment for reuse
Once equipment is received back at the UCLA study center, the following steps must be followed before returning equipment to inventory to be made available for reuse by another study patient:

- Each piece of equipment will need to be disinfected using Clorox wipes or equivalent
- Patient data is removed from the equipment by taking and transmitting a dummy BP and weight to the Ideal Life portal, so that any non-transmitted data that remains on the devices is transmitted to the previous patient’s Ideal Life portal account
- The BP monitor is reset by pressing all three buttons on the face of machine simultaneously while one of the four batteries already installed gets removed and then placed back in the machine. The machine will turn back on with a menu option for default factory setting, which will clear the memory of the device.
- The scale is reset by inserting a paper clip or similar into the small hole in the back or the scale near the battery hatch door while the scale is on, and holding it in place for five seconds, which will clear the memory of the device
- New batteries should be installed in both devices
- The serial numbers should be removed from the previous patient’s account in the Ideal Life portal

Equipment inventory tracking
Patient Confidentiality and Questions about the Study

Confidentiality & Patient Privacy

• The information that will be reviewed is the minimal necessary to identify potential research participants for this research.
• The information that will be obtained for identification of participants will not be reused or disclosed outside the research team, except as required by law.
• All study personnel will comply with HIPAA regulations.
• All participants will sign a HIPAA Research Authorization for Release of Personal Health Information for Research.
• To protect confidentiality of all electronic data, encryption or password protection software and secure network servers will be used to store data in this study.

The baseline survey will be conducted in private in the patient’s hospital room. Patients will be called on the telephone number they provide for the follow-up telephone surveys. The staff conducting follow-up telephone surveys and the centralized call center nurses will be centrally located at the UCLA study center in rooms designated for only this purpose.

All patient-identifying information will be kept confidential, and patients in the survey system will be identified by the unique PID assigned to them in PIWeb. Identifiable hard copy data will be maintained separately by the survey research group with limited access and kept only as long as needed to maintain consent files or to contact patients for follow-up surveys.

Research Related Injury, Patients Concerns or Complaints

In the event of a research related injury, or if patients have any questions, comments or concerns about the research, they are advised to immediately contact the local site principal investigator or Dr. Michael Ong at 310-794-0154, 10940 Wilshire Boulevard, Suite 700, Los Angeles, CA 90024.

If patients wish to ask questions about their rights as a research participant or if they wish to voice any concerns they may have about the study to someone other than the researchers, they should call the Office of the Human Research Protection Program at (310) 825-7122 or write to Office of the Human Research Protection Program, UCLA, 11000 Kinross Avenue, Suite 102, Box 951694, Los Angeles, CA 90095-1694.
APPENDIX A: Survey Instruments

Components of the Baseline Survey:

- An overall health status question
- REALM-R -- Rapid Estimate of Adult Literacy in Medicine, Revised – To assess how familiar the patient is with some basic medical words.
- Self-Care of Heart Failure Index – To assess the patient’s ability to care for their heart failure.
- Minnesota Living with Heart Failure Questionnaire – To assess how much the patient’s heart failure has affected their life.
- Lubben Social Network Scale – To assess the patient’s social relationship with friends and family.
- Medical Care Questions – To assess how much family members and friends are involved in assisting the patient with health care.
- Geriatric Depression Scale – To assess potential depression.
- Advance Directive Question
- Demographics
- The TIBI questionnaire will also be administered at baseline

Components of the 7-day survey:

- An overall health status question
- CTM-3 – To assess the patient’s view of the care transition from hospital to home
- Hospital Questions – To gather information on hospital usage since the prior survey
- ER Questions – To gather information on ER usage since the prior survey
- Medical Visit Questions – To gather information on medical visits since the prior survey
- Geriatric Depression Scale – To assess potential depression.
- Minnesota Living with Heart Failure Questionnaire – To assess how much the patient’s heart failure has affected their life.
- Self-Care of Heart Failure Index – To assess the patient’s ability to care for their heart failure.
- MMAS-8 – To assess medication adherence

Components of the 28-day survey:

- An overall health status question
- Hospital Questions – To gather information on hospital usage since the prior survey
- ER Questions – To gather information on ER usage since the prior survey
- Medical Visit Questions – To gather information on medical visits since the prior survey
- Geriatric Depression Scale – To assess potential depression.
- Minnesota Living with Heart Failure Questionnaire – To assess how much the patient’s heart failure has affected their life.
- Self-Care of Heart Failure Index – To assess the patient’s ability to care for their heart failure.
- MMAS-8 – To assess medication adherence
• **Lubben Social Network Scale** – To assess the patient’s social relationship with friends and family.

• **Medical Care Questions** – To assess how much family members and friends are involved in assisting the patient with health care.

• **Demographics**

• **WHO HPQ - Absenteeism and Presenteeism Short Form** – Questions about patient’s work in order to assess the impact of missed days from work.

**Components of the 180-day survey:**

• An overall health status question

• **Hospital Questions** – To gather information on hospital usage since the prior survey

• **ER Questions** – To gather information on ER usage since the prior survey

• **Geriatric Depression Scale** – To assess potential depression.

• **Minnesota Living with Heart Failure Questionnaire** – To assess how much the patient’s heart failure has affected their life.

• **Self-Care of Heart Failure Index** – To assess the patient’s ability to care for their heart failure.

• **MMAS-8** – To assess medication adherence

• **Lubben Social Network Scale** – To assess the patient’s social relationship with friends and family.

• **Medical Care Questions** – To assess how much family members and friends are involved in assisting the patient with health care.

• **Demographics**

• **WHO HPQ - Absenteeism and Presenteeism Short Form** – Questions about patient’s work in order to assess the impact of missed days from work.

• **The TIBI questionnaire will also be administered during the 180-day survey**

• **Survey Conclusion Questions**

**Components of the abbreviated 180-day survey:**

• **Minnesota Living with Heart Failure Questionnaire** – To assess how much the patient’s heart failure has affected their life.

• **Hospital Questions** – To gather information on hospital usage since the prior survey

• **Survey Conclusion Questions**
APPENDIX B: New York Heart Association (NYHA) Classification

Heart failure patients experience various symptoms such as limitation in daily physical activity, fatigue, palpitation, or dyspnea. Based on existence and severity of the symptoms, patients are classified into 4 groups, and the classification is recorded in PIWeb for all study patients.

<table>
<thead>
<tr>
<th>Class</th>
<th>Patient Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I (Mild)</td>
<td>No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea (shortness of breath).</td>
</tr>
<tr>
<td>Class II (Mild)</td>
<td>Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, palpitation, or dyspnea.</td>
</tr>
<tr>
<td>Class III (Moderate)</td>
<td>Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, palpitation, or dyspnea.</td>
</tr>
<tr>
<td>Class IV (Severe)</td>
<td>Unable to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken, discomfort is increased.</td>
</tr>
</tbody>
</table>

Table Extracted from Heart Failure Society of America website at http://www.abouthf.org/questions_stages.htm
APPENDIX C: Intervention Group – Pre-Discharge Education

HF basics
It is important to educate the patient in a simple and comprehensive way. For this purpose the educational material will be provided to each patient in a booklet which will help the study nurse to structure teaching to patients.

The main goal is to educate the patient about his or her diagnosis, and key lifestyle measure using a teach-back approach.

Here are examples of some teach-back questions:
1) What is the name of your water pills or diuretic?
2) What weight gains would you report to yourself? How do you weigh yourself?
3) What foods have you been told to avoid? Name high sodium foods.
   (Emphasis should be placed on a low salt education).
4) What changes in yourself would prompt you to call the doctors?

Daily assessment

HF medication
The study nurse will educate patient regarding various heart failure medications and the indications of each category:

- What medications to take
- Review each medication’s purpose
- Review dosage and important side effects to watch out for
- Make sure patient has a realistic plan about how to get the medications (use teach back approaches)

Low salt eating plan
Fluid intake
Physical activity

Study Process and Equipment
The study nurse will educate each patient on use of the wireless remote monitoring devices. The study nurse will demonstrate to the patient how to use the weight scale and BP cuff and BP manager, and teach the patient how to set up the communication device (cell pod) so that their measures are transmitted daily. The focus should be on relating the self-care discussed with the patient with use of the equipment. Teach back methods should be used to ensure that the patient knows how to use the equipment, and patients and/or caregivers will be asked to demonstrate proficiency with using the equipment prior to discharge. The patient should demonstrate putting on the BP cuff, standing on the scale, and going through the symptom questions. Patients will be given a toll free number to report any technical problems and obtain technical assistance as needed.
Pre-bundling of equipment at UCLA and CSMC enables the study nurse to transmit readings with a patient in the hospital. The study nurse will receive an automated email in real-time confirming a successful reading and transmission. If the confirmatory email is not received, the study nurse can replace the cell pod with another one. The bundled serial numbers for these two sites were entered into the Ideal Life portal by a UCLA study team member in advance of the sets being given to patients to enable this additional testing. Other sites did not test the transmission, but they were able to test the devices’ ability to take readings.

In addition, the study timeline and when to expect call center nurse calls and survey calls will be discussed. And the patient will be reminded that the study equipment will be returned using prepaid and preaddressed shipping materials that will be sent to them upon the end of the six month study period.

**Follow-up care**

The patient will be asked whether there is a preference in terms of day and time to be called by call center nurses. A sheet with name and photo of three call center nurses will be given to patients to familiarize them with the nurses who will call them after discharge for a better hand-off.

The study nurse will work with each patient to:

- Encourage attendance at post-discharge appointments for clinician follow-up
- Elicit input from the patient on the best time and date of the appointment
- Make sure the patient understands the importance of such services
- Confirm the patient knows where to go and has a plan about how to get to an appointment
- Review transportation options and other potential barriers that might keep patients off their appointments.

The study nurses shall not schedule an appointment for the primary outpatient provider. The goal is to encourage and empower patients to actively inquire and achieve their own healthcare needs. If patients inform the study nurses about a pre-scheduled appointment with their primary heart failure provider, or the post-discharge appointment has been set, such information could be entered in the Communication Form in the PIWeb.

The patient should be educated by the study nurse about the appropriate steps to take or whom to first call if a problem arises. The study nurse will discuss with patient:

- A specific plan of how to contact their primary heart failure provider, which could be a cardiologist or a primary care provider depending upon who the patient identified during the enrollment process
- What constitutes an emergency and based on symptoms when to call a doctor versus when to go to emergency room
Appendix D: Diagram of BEAT-HF patient enrollment, randomization, intervention, and timeline

**Daily screening at each medical center:**
- Age ≥ 50 years
- Actively treated for HF
- Speaks English, Spanish, Persian, or Russian

**Approach, assess ability to consent, obtain informed consent, HIPAA authorization**

**Baseline survey**

**Randomization (1:1)**

**Control**

**Intervention**

**Exclusions**
- Lacks ability to use intervention
- No telephone
- No provider after discharge
- Unstable housing
- Resides in or discharged to SNF
- Chronic hemodialysis
- Organ transplant/LVAD recipient or listed
- AMI, PCI or valve surgery during current stay
- Critical aortic stenosis
- Hospice
- Non-California resident

**Hospital discharge**

**Scheduled RN Calls**

- 7 day survey call
- Week 1
- Week 2
- Week 3
- Week 4

- 30 day survey call
- Month 2
- Month 3
- Month 4

- 180 day survey call
- Month 5
- Month 6

- End of Study

**Usual care**

**End of Study Equipment Return**

**Call Center RN telephone contact with patients and their physicians in response to tele-monitoring alerts**