A Technology-Assisted Care Transition Intervention for Veterans with Chronic Heart Failure or Chronic Obstructive Pulmonary Disease

Version 16, February 24, 2021

NCT02632552

HUMAN SUBJECTS RESEARCH PROTOCOL

Project Title: A Technology-Assisted Care Transition Intervention for Veterans with Chronic Heart Failure or Chronic Obstructive Pulmonary Disease

Protocol Version and Date: Version 16, February 24, 2021

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Institution(s):
Bedford ENRM VA Hospital (coordinating site);
Additional study sites: VA Boston Healthcare System, Hines VAMC, Iowa City VAMC, Palo Alto VA Healthcare System, Northeastern University

1.0 Objective and Specific Aims:

Only analysis (of data and interviews) and post-intervention semi-structured participant interviews will occur at Bedford ENRM VA Hospital. Patient recruitment, surveys, required study interviews, and all other study activities will occur at four test sites: Boston, Iowa City, Hines, and Palo Alto VAs. Bedford study staff will travel to three study sites for team meetings and to conduct interviews. No data will be collected at Northeastern University (NU), nor will staff from NU be involved with data collection—NU will be developing the animated intervention.
All data will be housed on a secure server at Bedford. We will submit an amendment to develop a data repository.

Transition from hospital to home places patients in jeopardy of adverse events and increases their risk for rehospitalization. CHF is the most prevalent chronic condition among U.S. adults and COPD is the third leading cause of death in the U.S. Both CHF and COPD represent significant burdens for the VHA healthcare system. Care transitions can be supported through multi-component interventions, but are costly to implement. Virtual nurses provide an effective medium for explaining health concepts to patients, and previous work indicates patients find virtual nurses acceptable. We will implement and evaluate a virtual nurse intervention named "Annie" to provide automated, tailored, and timely support to Veterans transitioning from hospital to home. As effective care transition interventions incorporate

both inpatient and outpatient components, our virtual nurse will first engage with patient onscreen during their inpatient stay and then via text message post-discharge. This project has the potential to improve the care transition experience for patients, caregivers and healthcare providers.

Partnering with operations stakeholders, we propose an effectiveness-implementation hybrid type 1 trial, a design that involves testing the effects of an intervention while also gathering information about its implementation. Guided by the Socio-Technical Framework for Implementing Health Information Technology, we will pursue the following **three specific aims**:

Aim 1. (Pre-implementation) Refine methods and collect formative measures to guide implementation

Setting: Northeastern University (software development) and Bedford VA (beta testing)

Sub-Aim A1: We would like to add Bedford as a beta test site. In order to prepare our intervention components for pilot testing, we would like to beta test the components separately with a small group of patients here at VA Bedford. We will gather feedback on usability issues and suggestions for improvement. In the beta testing phase here at VA Bedford, we would ask outpatients patients with CHF or COPD to do one of two things:

Group 1: Look at and interact with a virtual nurse computer character on a touchscreen tablet computer who will teach them about the pillars of a good care transition, and also complete a baseline and technology usability survey, and a short semi-structured interview about their experiences interacting with the virtual nurse.

Group 2: Receive text messages from VA's automated text messaging system about the pillars of a good care transition, and also complete a baseline and technology usability survey, and a short semi-structured interview about their experiences using the automated text messaging system.

Sub-Aim B: Adapt previously-tested discharge messaging protocols for Annie's outpatient texting

Sub-Aim C: Conduct formative evaluation fieldwork to guide our trial (Aim 2)

Aim 2. (Implementation) Conduct a randomized trial of the technology-assisted care transition intervention

Setting: Inpatient services of four purposefully-selected VHA facilities - Palo Alto, Boston, Hines, and Iowa City

Sample: Veteran inpatients with CHF or COPD and their clinical teams

Implementation Protocol: Centralized implementation support by dedicated discharge assistants

Effectiveness Trial: Patient-level randomization to Annie or attention control

Aim 3. (Evaluation) Evaluate Annie, including effectiveness, implementation, and budget impact

Hypothesis: Compared to control, patients randomized to Annie (inpatient onscreen coaching and outpatient automated texting) will have lower urgent care utilization (ED

visits and hospitalization (comparing pre-hospitalization versus post-hospitalization)
Setting: Palo Alto, Boston, Hines, and Iowa City VAs

2.0 Background and Significance

2.1 Background

Transition from hospital to home places complex patients in jeopardy of adverse events and increases their risk for use of urgent care (emergency department visits and hospitalizations). In a study of Medicare patients, nearly 20% were rehospitalized within 30 days[1], and similar results have been found at VHA facilities[2]. Patients and their families are unprepared for what awaits them at home[3], partially due to deficiencies in transferring information and supporting self-management[4-7].

For Veterans with CHF or COPD, the transition from hospital to home is a vulnerable period, placing them at great risk for adverse event and risk of rehospitalization. Nurse inperson care transition interventions are effective, but are resource intensive. Few CTIs have used advanced patient-directed technologies, an effective means to augment care transition interventions. The relational agent and tailored communication technologies that we will evaluate are a means to overcome the constraints of traditional nurse-based/home visit centric interventions and will make it feasible to coach Veterans with CHF or COPD on an ongoing basis, regardless of their distance from VA facilities.
Patient-level care transitions can be supported through multi-component, evidence-based interventions[8-12]. Parker and colleagues performed a systematic review to study characteristics associated with improved care transitions[13] and decreased urgent care use. Many of these interventions focused individually or on a combination of discharge planning, discharge support, geriatric assessment, and educational approaches.

2.2 Preliminary Studies

In an innovative series of projects, Dr. Timothy Bickmore (co-investigator on this project) developed virtual nurses and coaches to support patient and provider behavior. These "relational agents" are on-screen human-like representations of personalities that use gestures, words and phrases based on psychology and communication science to engage a patient in a simulated face-to-face dialogue. The virtual nurse talks using synthetic speech and animation, and patients respond by selecting from a multiple-choice list of phrases on a touch screen.

Our pilot work in VHA also indicates that Veteran patients find virtual nurses acceptable and, in some cases, preferable to in-person or web-based reports. A pilot study conducted by Dr. Steven Simon of 30 Veterans at VHA Boston examined the use of a virtual nurse for substance use screening. Dr. Simon demonstrated that more than three-fourths of the participants (23/30; 77%) rated their experience with the virtual nurse as "positive." Veteran reasons for preferring the virtual nurse over a human interviewer for the screening included its ease of use and neutrality (not judgmental). One Veteran noted that the virtual

nurse was "easier to understand, simple to use, and quick." When queried about quickness, he appreciated that he could read the virtual nurse's screening questions at his own pace, rather than hearing them read at the pace of the human interviewer. In a second pilot conducted by Dr. Simon, Veterans were assigned to complete substance use screening with a virtual nurse or a mental health assistant, an online interactive tool within the Computerized Patient Record System. Veterans were more satisfied with the virtual nurse than the mental health assistant (5.96 vs. 5.17) and were more likely to want to continue working with the virtual nurse than the mental health assistant (5.67 vs. 5.13). Veterans were also more likely to describe their relationship with the virtual nurse as a close friend rather than a stranger (4.33 vs. 3.83). Dr. Simon's work suggests that Veterans with CHF or COPD, even if older or lacking computer or health literacy, will be able to engage meaningfully with a virtual nurse.

2.3 Significance

Chronic heart failure (CHF) and chronic obstructive pulmonary disease (COPD) are leading reasons for admission and re-admission in VA facilities. Multi-component care transition interventions (CTIs) can be effective at reducing re-admissions, but they have not been widely implemented. This project will adapt the Coleman CTI to address the needs of Veterans with CHF or COPD throughout the care transition experience. Utilizing relational agent technology (an anthropomorphized computer program designed to simulate a personality) pre-discharge to train patients and clinical teams on the components of a successful care transition, and the VA's newly developed HealtheDialog computer tailored health communication system post-discharge to exchange text messages with patients and family caregivers, we will support improved communication and provide targeted self-management support.

3.0 Research Design and Methods

3.1 Drug/Device Information Not Applicable

3.2 Type of Study

Pre-Clinical Trial Activity: Beta testing (VA Bedford):

Beta testing of the technology intervention components (relational agent tablet, automated text messages). This is not a treatment study; we are simply gathering feedback on the technology for their refinement prior to the larger pilot and subsequent clinical trial.

Clinical Trial (VA Boston, Palo Alto, Hines, Iowa City):

This is an effectiveness-implementation hybrid type 1 trial, a design that involves testing the effects of an intervention while also gathering information about its implementation. We will conduct beta testing to refine existing technologies to the VHA care transition setting (Aim 1) (developed at Northeastern University, tested at Bedford VA). This will be followed by a multi-site hybrid type 1 randomized trial (Aims 2 and 3) evaluating clinical effectiveness and gathering data on the implementation of the intervention in twelve

clinical teams with the support of a dedicated discharge assistant at each of the four sites (Boston, Iowa City, Hines, Palo Alto). Our study will use a purposeful sample of facilities and patients (not at Bedford ENRM VA Hospital).

3.3 Study Procedures

a. Pre-Clinical Trial Activity - Beta testing (Bedford):
In order to test our intervention components prior to the larger pilot and subsequent clinical trial, we would like to conduct beta testing with outpatients at VA Bedford.

Beta testing at VA Bedford:
Patients with CHF or COPD who are willing and able to interact with technology will be invited to participate in the beta testing. We will identify patients through chart reviews and with the help of suggestions from physician researchers at Bedford. Patients will sign an informed consent.

The patients will be entered into one of two groups:

Group 1 "Relational Agent": Look at and interact with a virtual nurse computer character on a touchscreen tablet computer who will teach them about the pillars of a good care transition, and also complete a baseline and technology usability survey, and a short semi-structured interview about their experiences interacting with the virtual nurse. They will receive a gift card ($30) for participation to compensate for their time. We aim to recruit 20 patients.

Group 2 "Text Messages": Receive text messages from VA's automated text messaging system about the pillars of a good care transition, and also complete a baseline and technology usability survey, and a short semi-structured interview about their experiences using the automated text messaging system. Receive and respond to a few text messages per day for up to two weeks. The interview will be over the phone. We will contact participants 3-5 days after they start receiving text messages. If it is determined that there is more to discuss, we will contact them again after the 14 days of text messages (optional and the participant can opt out of the follow up). A gift card ($30) will be mailed to participants to compensate for their time. Texts will imitate messages meant for a patient released from the hospital and may not directly apply to the participants in this beta test.

We aim to recruit 20 patients (10 per group).

The interviews will be audio recorded and transcribed by VA SLC transcription services. Data will be kept on the VA server in a protected folder: Q:\DATA\Hogan TACT CHF COPD IIR and any hardcopy data will be kept in a locked VA office in a locked filing cabinet (building 70 room 259).

Touch-Screen and Content Refinement Work:
The touch screen and content refinement work associated with Aim 1 will be conducted by Dr. Bickmore's Relational Agents Group at the College of Computer and Information Science at Northeastern University. Dr. Bickmore will oversee touch screen and content refinement. Once refinements are completed, beta testing will be conducted with Veterans at Bedford VAMC.

b. Clinical Trial Procedures

Clinical Trial Overview (Palo Alto, Boston, Hines, Iowa City):
Our setting is the inpatient services of four VA medical centers, Palo Alto, Boston, Hines, and Iowa City VA. Analyses will be done at Bedford ENRM VA Hospital and Hines VAMC.

Patients will receive standard medical care as expected.
If they decide to participate in this research study, they will be randomized to receive one of two interventions to support their transition back to home. Patients will be asked to complete a baseline survey about demographics and pre-discharge experience. Patients will receive a short education on care transitions (either a PowerPoint for control or on-screen Annie intervention training on the procedures).

Inpatient: During the inpatient stay, Annie will appear on a computer touch screen and will educate Veterans with CHF or COPD about the important components of a care transition as well as how to send and receive text messages on their mobile phone. Outpatient: Following discharge to home, Annie will continue to coach Veterans and improve post-discharge access to care through two-way computer-tailored text messaging made possible by VHA's new HealtheDialog system. The goals of the text messages are to remind Veterans of care transition pillars, assess whether Veterans have questions or are experiencing symptoms, provide assessment feedback, and to motivate Veterans to ask questions and share information with their primary care team. These are health coaching and motivational text messages. The control group will receive a maximum of four to six messages over the 30-day intervention period for the purpose of keeping them engaged in the study. All participants will be contacted 7 and 30 days after discharge to conduct follow-up assessments (surveys over the phone), each survey taking 30 minutes or less.

Recruitment and Participation for in-patient Veterans (Not at Bedford):

All patients will receive standard medical care on the general medical wards at VA medical centers, Palo Alto, Boston, Hines, and Iowa City. Each site PI is a clinician. On average, for each facility, the medical teams admit approximately 200 patients per month. All facilities have access to subspecialty services, diagnostic radiology, pulmonary therapists, and cardiac monitoring on these medical wards. At discharge, patients are provided a printed list of discharge medications, follow-up instructions, and discretionary

patient education materials, with some variation by site. As part of our pre-implementation formative evaluation fieldwork, we will document these variations to further define differences in standard care by site. Given that the intervention is randomized at the patient level, within-site, we expect these variations to be balanced. For pilot testing in aim 1 at VA Boston, we aim to recruit 60 participants (30 intervention, 30 control). For the study, our goal is to recruit 600 (200 per site) Veterans from among 1,913 with COPD/CHF as primary diagnosis and then expand to those within the total pool of 19,128 who have secondary diagnoses of CHF/COPD at the four study sites (Boston, Hines, Iowa City, Palo Alto). These procedures will not be conducted at the Bedford ENRM VA Hospital.

To help us to ensure follow up survey completion, we will send Veterans a letter or postcard to remind them of the upcoming appointment we set up with at the time of enrollment.

To help us ascertain baseline data and one month follow up data, we will need to access additional data. Some of this data will be obtained through pre and post intervention chart reviews. We will also use VA CDW and Medicare data to examine urgent care and emergency department utilization including visits, observations, and admissions one month post hospitalization for Veterans with Chronic Heart Failure or Chronic Obstructive Pulmonary Disease. We will not be requesting Medicare data until after the trial period ~30 days (Spring 2017 through Summer 2020). We will need Medicare data for calendar year 2016-2020 for an estimated 600 total participants.
As is common in many households, there may be some Veterans who own a cell phone, but share that phone with a caregiver (e.g., a spouse) in their life. If a Veteran has a cell phone but shares it with a caregiver, setting up the automated text messaging system to send messages to that cell phone is reasonable given the study parameters.

If a Veteran is interested in participating in the study but does not have a cell phone they call “their own” but they do have a caregiver (e.g., a spouse) who has a cell phone, and both the Veteran and caregiver agree, we would like to use the caregiver’s cell phone number to receive the automated text messages which they would then share with the Veteran. Note that in such cases, the target population for the study is still the Veteran. The caregiver’s involvement in such cases would be only to facilitate the delivery of the automated text messages to the Veteran.

Post-Clinical Trial Participation Interviews As described below, a small subset of participants (n=25) who completed the 30- day phone survey will also be invited to participate in a follow-up audio-recorded phone interview. These interviews will be conducted by project staff at Bedford VAMC and Hines VAMC. The phone interview portion will last up to 30-45 minutes. Participants who complete an interview will be mailed a $10 incentive to thank them for their time. The purpose of the follow-up phone interviews is to gather richer, qualitative data about their intervention experiences to

complement the 30-day phone survey. If a participant should refuse to participate in the interview, we will approach an additional participant. The interview is not required. In cases where a participant chooses not to complete a follow-up phone interview, we will still include their responses to the phone survey in our analyses.

Given the possibility that some participants were assisted with the intervention by an informal caregiver in their life, we would like to invite these caregivers to participate in an interview. These interviews will help us understand the full range of experiences associated with the intervention. Following completion of the interview, we will mail a $10 incentive to the participant to compensate them for their time. We will ask each Veteran we interview if a caregiver assisted them with texting. Their response will be documented on the referral to caregiver document (approved by this IRB dated May 16, 2019). As such, there is the possibility of interviewing up 25 caregivers; however, we imagine that not every Veteran will have had assistance so we anticipate that we will interview up to 15 caregivers. Upon referral from the Veteran, we will use the phone number provided to us to make initial contact with the caregiver. If they are not interested in participating there will be no further contact; however, if they agree to be interviewed, we will offer to set up a date and time that best fits their schedule. Like the Veteran interviews, all caregiver interviews will be conducted via telephone from Bedford and Hines VAMCs. At the time of the call, caregivers will consent using the script that we developed. Following this, each caregiver will respond to a few demographic and background questions and then sit for the semi-structured interview. Following completion of the interview, we will mail a $10 incentive to the caregiver to compensate them for their time. Like the Veteran interviews, interviews will be audio-recorded and transcribed for analysis. Interview topics will reflect the dimensions of our study's conceptual framework (i.e., the sociotechnical model) and will last 30-45 minutes.

Post-Trial Clinical Staff Interviews (Bedford activity taking place on-site at Boston, Palo Alto, Iowa City, and Hines):

We will conduct semi-structured interviews with clinical staff to learn about their experiences with the intervention. Site discharge assistants will invite clinical staff involved in the intervention to participate in interviews. These interviews will be conducted by study staff, as Bedford activity.

3.4 Data Collection

Pre-Clinical Trial Activity – Beta Testing (Bedford)

Beta testing will be conducted at VA Bedford in order to test our intervention components (relational agent, texting) prior to the larger pilot and subsequent clinical trial.

The testing group will consist of Drs. Hogan, Houston, Steven Simon, and Timothy Bickmore, as well as the designated discharge (research) assistant at VHA Boston. The touch screen and content refinement work associated with Aim 1 will be conducted by Dr. Bickmore's Relational Agents Group at the College of Computer and Information Science at Northeastern University. Dr. Bickmore will oversee touch screen and content refinement. Once refinements are completed, the beta testing will be conducted with Veterans at Bedford VAMC.

The Annie Implementation Group will consist of Drs. Hogan, Stephanie Shimada, and Bonnie Wakefield, as well Drs. Simon and Heidenreich in their roles as sites PIs, and their corresponding site discharge assistant. The Annie Evaluation Group will consist of Drs. Houston, Keith McInnes, Bridget Smith, and Neil Evans. As project coordinator, Ms. Richardson will support the communication and documentation needs of this group. Dr. Houston will lead the evaluation group. Each working group will have weekly meetings during the years of the study when they are active and biweekly meetings with the overall team to ensure coordination of tasks.

Pre-Clinical Trial Activity: Site Visits (Bedford)
For Sub Aim C: The study team will conduct semi-structured interviews at three trial sites with clinical staff and as part of site visits. These site visits will be led by the PI, Dr. Hogan, and will be organized and scheduled by local study staff. We will work with the discharge assistants and site PIs in advance of each visit to compile a list of clinical staff and other key informants (e.g., quality improvement officers). Recruitment of other clinical staff and key informants will proceed through an accumulative or "snowball" sampling strategy in the course of the interviews. Recruitment of clinical leadership and clinical team members will continue until 1) there is redundancy in referrals and 2) we have sufficient data to support our implementation goals. We plan to recruit 12-15 clinical participants from each site. All interviews will be conducted under the approval of the Bedford study site, using Bedford consent forms, and will be one-on-one, semi-structured, and audio-recorded, lasting about 30 minutes. At the start of each interview, participants will be asked to complete a short questionnaire to document their professional background, training, and work experience. Interview topic areas addressed will include current care transition practices, programs, and related interventions at the facility, use of technology to support care processes, characteristics of the clinical environment and corresponding implications for implementing novel, technology-based interventions, and pros and cons of using the kinds of technology specific to the Annie intervention to interact with older patients. The target for the implementation protocol is the inpatient general medical team at the four sites. These teams include nurses, nurse assistants, attending physicians, and resident physicians in training. Our goals are to:

- Train dedicated discharge assistants at each study site and equip them with tools to facilitate the initial rollout of the Annie (onscreen and texting facilitation) intervention
- Monitor the rollout of the intervention and provide feedback to the discharge assistants

- Evaluate the influence of the Annie intervention on the inpatient clinical teams
- Evaluate potential patient safety and clinical risks associated with the outpatient automated texting component of the Annie intervention

Clinical Trial Activity (Not Bedford)
At the four study sites (Boston, Iowa City, Hines, Palo Alto), this hybrid Type 1 randomized trial "The Annie intervention" is targeted primarily at patients and not clinical units so randomization is at the patient level. We will also collect data about various cluster-level factors to evaluate variations in implementation, and will incorporate in our data models as random effects.

As in the pre-implementation pilot, patients from the four sites will be randomized to the full Annie intervention (onscreen inpatient and texting outpatient), or the active comparison control. Informed consent will explain to the patients that they will receive one of two interventions to support their transition back to home.

After consent and baseline surveys at the four sites, Veterans will be randomized. The randomization program will use a randomization table using a permuted block design (block sizes of five) developed by our statistician. Each VHA site will have a separate randomization table. As all patients receive some intervention (active control or Annie), they will remain blinded to group assignment. Veterans randomized to Annie or control in the pilot experiment will be re-contacted seven days post-discharge to assess the Care Transition Measure. Feedback to inform the refinement of Annie's interface and content will be gathered through interviews conducted with Veterans immediately after exposure to the Annie interface. Interviews will address challenges with the touch screen and display, organization of content displayed, and clarity of instructions and feedback that Annie provides. This information will be used to inform iterative rounds of interface modifications. In our Aim 1 work, we are interested in understanding the usability experiences of Veterans with CHF and COPD. Thus, ten Veterans (five with CHF and five with COPD) will be recruited for interviews.

The following table is a map describing each of the measures and when they will be utilized.

#	Measure/Instrument	Phase/Timing and Description
SECTION A: Baseline		
1	Trial Baseline Questionnaire	At baseline of the testing for all participants
SECTION B: Immediate Post-Exposure		
2a/b	Trial Tablet/Agent Usability Questionnaires	Testing for the tablet component, questions flagged for intervention vs. control after interaction with the tablet
SECTION C: 7-Day Outcomes		
3	7 Day Post Discharge Care Transition Measure	At 7 days post discharge
SECTION D: 30-Day Outcomes		
4	Trial CHF Pre/Post Outcomes Questionnaire	At baseline and follow up, for patients with CHF of the testing
5	Trial COPD Pre/Post Outcomes Questionnaire	At baseline and follow up, for patients with COPD of the testing
6	Trial Outcomes Post Questionnaire	At follow-up of the testing for all participants
7	Trial Texting Usability Outcomes	Testing for the texting intervention component at follow up
8	Patient Semi-Structured Interview	At follow up of the testing for a small subset of participants
9	Caregiver Semi-Structured Interview and Background Questions	At follow up of the testing for a small subset of caregivers

We will begin our dissemination efforts when Aim 1 work is completed at the end of year 1 and then further expand our dissemination efforts in years 4 and 5 once implementation and clinical effectiveness data from the trial have been analyzed. Dissemination of lessons learned from implementation of Annie will begin in Year 3 and dissemination of trial evaluation outcomes will begin in year 5.

The following table lists our key data elements and data sources (see appendices):

Key Data Elements, and Data Sources (See Appendices for measures)	CDW Data	Patient Survey	Texting Accesses/data
Demographic characteristics	B	B, F	
Diagnoses/Comorbidities (CIRS-G)	B	B,F	
Rapid Estimate of Adult Literacy in Medicine (REALM) -Short Form		B	
Computer Attitudes Measure (CAM) and previous texting experience		B	
Patient-reported "red flags" (P4)		F	F
Patient access to Annie		F*	F
Care Transition Measure (CTM) (P1-4)		F	
Follow-up no-show rates (P3)	F	F	
Patient-provider communication		B,F	
Self-efficacy for managing chronic disease		B, F	
Health distress		B, F	
Self-report ratings of the relational agent		I*,F*	
1-month rehospitalization	F	F	
System Usability Scale (SUS)		I*,F*	
Technology Assessment Measure (TAM)		I*,F*	
Relational Agent Engagement Scale		I*	
Working Alliance Inventory (WAI) for collaborating with Relational Agent*		I*	
Preparedness for discharge		I,F	
User experience interviews		F**	
P (1,2,3,4) = Pillars of Care Transition Intervention Model; * intervention only, ** subset of intervention only, B= baseline, I= Immediate inpatient postintervention, and F = 1-month Follow-up			

List of data elements:

Data source	Data elements
CDW: Consult	Demographics, clinical diagnoses, procedures, and services
CDW: Inpatient	Demographics, clinical diagnoses, inpatient utilization
CDW: Outpatient	Demographics, clinical diagnoses outpatient utilization and telephone encounters

CDW: Patient	Demographics
CDW: Purchased Care	Fee Basis Utilization
CDW PSSG Geocoded Enrollment File	Priority category (as an indicator of whether Veterans have a copayment for all, some, or no medications and service connection status) and zip code
Vital Status File	Date of death
U.S. Census Data	Zip code level socioeconomic status
MCA Files	Cost data for VA healthcare use
CDW: Appointment	Dates of missed appointments
Medicare Denominator File	Demographics
Medicare claims data (Medicare Provider Analysis and Review [MedPAR] files, Outpatient files, Carrier files, Durable Medical Equipment [DME] files, Home Health),	Healthcare utilization and costs

Post-Clinical Trial Data Analysis (Bedford and Hines VAMCs)

Aim 3 data collection procedures will consist of Corporate Data Warehouse administrative records, baseline data collection from participants, usage statistics of the HealtheDialog texting system, a follow-up participant call to assess outcomes, and Annie user experiences from the four sites. All Aim 3 data will be analyzed at both ENRM VA and Hines VAMC.

3.5 Analysis Plan

For beta testing at VA Bedford:
We are the parent site to a multi-site clinical trial. We originally decided not to do any patient recruitment at Bedford, but to improve the pilot testing of our intervention components, we would like to add Bedford as a beta test site. In order to prepare our intervention components for pilot testing, we would like to beta test the components separately with a small group of patients at VA Bedford. We will gather feedback via surveys and semi-structured interviews on usability issues and suggestions for improvement so that we are better suited to move forward with pilot testing at VA Boston as well as the larger multi-site trial.

For all sites: Our procedures will consist of Corporate Data Warehouse administrative records, baseline data collection from participants, usage statistics of the HealtheDialog texting system, a follow-up participant call to assess outcomes, and Annie user experiences at the sites.

For Sub-Aim A (conducted at the Bedford VA): The independent variable will be randomized group assignment to the intervention (the Annie interface/content) or the control. Scores on the Care Transition Measure (CTM), a 15-item uni-dimensional measure of the quality of preparation for care transitions will be utilized. Randomization beta testing will be at the patient-level. We will compare the effectiveness of the pre-discharge component (e.g., not the post-discharge text messaging component) of the Annie intervention compared with control. The goal of this analysis will be to determine impact on quality of care transitions as indicated by CTM scores. Each of the 15 CTM items has a 4-point Likert response scale (strongly agree; agree; disagree; and strongly disagree) with the lowest possible score being 0 and the highest possible score being 100 and higher scores indicating a better quality care transition.

For Sub Aim C: The study team will conduct semi-structured interviews at three trial sites with clinical staff as a part of site visits. These visits will be led by Dr. Hogan and will be organized and scheduled by local study staff. All interviews will be conducted under the Bedford study site, using Bedford consent forms, and will be audio-recorded and transcribed into text. Consistent with RAP, we will use content analysis, including the constant comparative method, to identify and tabulate key themes emergent from the data regarding factors that could influence Annie implementation. We will develop an initial code list a priori, based on the dimensions of the Socio-Technical Framework. Within each of these dimensions, we will inductively develop additional codes and analyze the text for themes and patterns. Upon completion of deductive coding, a series of virtual analytic retreats (likely two in total) will be held with members of the larger research team (Drs. Hogan, Houston, Smith, Wakefield, and the site PIs), to examine the data contained within the dimensions and to review it inductively for any further themes. Our formative evaluation findings will inform the training and preparation of the discharge assistants who will provide support for Annie's rollout. Training and development resources are anticipated to include, but are not limited to, recommended best practices for recruitment, inventories of local barriers, scripts, checklists, and FAQ sheets to support steps in the enrollment process, and related reference materials about the technology.

All Aim 3 analyses will be done in partnership at ENRM VA and Hines VAMC. For Aim 3 effectiveness analyses, the independent variable will be group assignment (Annie or control) and all analyses will use an analyze-as-randomized intent-to-treat approach. In addition to measuring all rehospitalization, we will determine the relatedness of the rehospitalization to the index admission (relatedness defined as having COPD or CHF as a primary or secondary diagnosis on rehospitalization). Further we will assess the potential for prevention of the rehospitalization. There are several approaches to identifying potentially preventable rehospitalizations, including using software algorithms, and more rigorous manual chart/survey data reviews. We now propose to classify readmissions as possibly preventable using a gold standard review of all data from each patient.
We will measure pre-post trend in urgent care utilization. For an 18-month period pre-index hospitalization and a six-to-twelve month period post-hospitalization (depending on time of

recruitment, we propose to extract data, our primary effectiveness measure (urgent care utilization) and dates. This is a pre-post difference in differences analysis, comparing the number of urgent care utilizations per month before and after the index-hospitalization where randomization occurred. For this analysis, the outcome for each individual is a count of urgent care utilizations. We will use a count regression with the dependent variable being the post-hospitalization count of urgent care, using the pre-hospitalization count as a covariate in the model. For this outcome, we will also construct a linear regression model using the mean change in the number of urgent care utilizations by randomization group. Finally, we will conduct an interrupted time series analysis using the times of the urgent care utilization, the randomization treatment group, a marker for pre versus post-index hospitalization. In this model, we will look for a significant difference in change in the slope of urgent care utilizations pre-post-index hospitalization by randomization group. We will evaluate sustained community tenure, (number of days out of 30 days that the Veteran is in their own home (as opposed to inpatient or in the emergency department). For this measure, we will first explore the distribution of the outcome to assess whether it fits best as a count distribution or a difference in mean proportion of days. We will then conduct a bivariate analysis with the dependent variable (sustained community tenure) and the independent variable (randomized group assignment).

Power Calculations:
For our primary outcome measure, we first estimated a mean number of urgent care visits (ED and hospitalization) for the six months pre-randomization and six months postrandomization for each patient. We know that readmission rates are between 12.7% and 21% annually for our Veterans, and ED visits will be similar or higher per year (thus urgent care use = 25%-40%). Thus, we estimate a monthly rate of urgent care use of 3% (40% annual/12 months) of our sample of 600 patients (thus a mean of 18 utilizations per month). Using a pre-intervention rate of 18 for both intervention and control, and a postcontrol change of 1, assuming an alpha of 0.05, and we have power (0.8) to detect a difference of differences in change in mean urgent care utilization of 0.75 with a standard deviation equal to the control mean.

Our recruitment will occur over 24 months, post-discharge number of months of data will vary between six and twelve, and will extend back in time for up to 24 months, resulting in a total number of months between 24 and 36 for urgent care utilization. With these assumptions, we are powered to detect an effect size of 0.5 with an autocorrelation between 0.0 and 0.2.

Assuming a baseline rate of 1.0 and the mean exposure time to be 30 days, a sample of 300 patients in each group will achieve 80% power at a two-sided alpha level of 0.05 to detect a rate ratio of at least 1.0425. This calculation is based on a Poisson Regression with the number of 30-day sustained community tenure counts as the dependent variable and randomized group as a binary independent variable.

We will rely on established measures and techniques to examine patient experiences of the Annie intervention. Patient factors known to moderate current technology use like age, education, income, vision correction, technology attitudes, and previous text messaging experience will be measured at baseline as part of demographic questionnaires and other established instruments. Research assistants will query all participants in-person in order to collect baseline responses before discharge. Pre-intervention measures will also include constructs related to the Care Transition Pillars such as patient-provider communication (information sharing), health distress, and self-efficacy for managing chronic disease (self-management ability and confidence) in order to be able to compare evaluation outcomes to baseline levels. Research assistants will call patients for the collection of post-intervention measures. As a quantitative measure of user preferences, intervention patients will also provide responses to validated questionnaires related to their experience with the virtual nurse coaching and texting technologies, including perceived usefulness and overall system usability. As a quantitative measure of performance, activity logs from the texting system will be examined to determine the number of text messages initiated by the system and received by participants. Intervention patients will also be asked whether an informal caregiver assisted with participation in the intervention. Finally, to gain more in-depth information regarding the experiences of patients and any challenges that they encountered during the outpatient automated texting intervention, a sub-sample of intervention participants will be interviewed (again via telephone) (n=25). Interviews will be audio recorded and transcribed for analysis. The phone interview portion will last up to 30-45 minutes. Participants who complete an interview will be mailed a $10 incentive to thank them for their time. These interviews will be conducted by project staff at Bedford VAMC and Hines VAMC. Interview topics addressed with patient intervention participants are organized around the dimensions of the Socio-Technical Framework.

Given the possibility that some participants were assisted with the intervention by an informal caregiver in their life, we would like to invite these caregivers to participate in an interview. These interviews will help us understand the full range of experiences associated with the intervention. Following completion of the interview, we will mail a $10 incentive to the participant to compensate them for their time. We will ask each Veteran we interview if a caregiver assisted them with texting. Their response will be documented on the referral to caregiver document (approved by this IRB dated May 16, 2019). As such, there is the possibility of interviewing up 25 caregivers; however, we imagine that not every Veteran will have had assistance so we anticipate that we will interview up to 15 caregivers. Upon referral from the Veteran, we will use the phone number provided to us to make initial contact with the caregiver. If they are not interested in participating there will be no further contact; however, if they agree to be interviewed, we will offer to set up a date and time that best fits their schedule. Similar to the Veteran interviews, all caregiver interviews will be conducted via telephone from Bedford and Hines VAMCs. At the time of the call, caregivers will consent using the script that we developed. Following this, each caregiver will respond to a few demographic and background questions and then sit for the semi-structured interview. Following completion of the interview, we will mail a $10 incentive

to the caregiver to compensate them for their time. Like the Veteran interviews, interviews will be audio-recorded and transcribed for analysis. Interview topics will reflect the dimensions of our study's conceptual framework (i.e., the sociotechnical model) and will last 30-45 minutes.

The discharge assistants at each site (Boston, Iowa City, Hines, Palo Alto) will receive training and accompanying resources to support their work based on the findings of our formative evaluation fieldwork. The training will consist of two virtual seminars facilitated by the PI and Co-PI and during which the accompanying resources will be introduced. Discharge assistants will have the opportunity to provide feedback on both the training seminars and resources. To collect process-oriented data during Annie's implementation, we will solicit updates from the discharge assistants using a structured form that will be emailed to them once a week during the intervention period. Items on the structured form will ask about patients approached and enrolled, time spent on associated tasks, resources used, success stories, roadblocks, and feedback from patients or clinical team members.

To understand provider attitudes toward and perceptions of our care transition intervention, and the impact that the inpatient touchscreen and outpatient text messaging intervention components had on communication between providers and Veterans, we will identify providers who treated patients enrolled in the trial. Sampling will be done using CDW data to identify providers at our study sites who had outpatient encounters with Veterans enrolled in the trial for treatment related to CHF and/or COPD. The identified providers will receive an initial email with a link to a brief REDCap survey. After approximately 1-week, these providers will receive an email reminder to complete the brief REDCap survey if they have not done so already. Initially, the vision was to gather provider feedback about our intervention through interviews and possible post-trial site visits; however, due to the COVID-19 pandemic, we cannot travel for site visits and we want to minimize the potential burden that this data collection presents to providers as much as possible. Our brief REDCap survey should take approximately 5 minutes for providers to complete.

We will conduct a cost-identification analysis (CIA) to assess cost of providing the Annie intervention, and a budget impact analysis (BIA) to assess impact on costs to a VHA medical center of implementing the intervention. To estimate costs and the potential budget impact for a facility implementing Annie, we will obtain cost data from VHA Managerial Cost Accounting (MCA) datasets (formerly known as Decision Support System (DSS) National Data Extracts), consultation with the Health Economics Resource Center, and consultation with the study sites. To estimate the cost of the intervention, we will calculate the costs of implementing the virtual nurse intervention and usual care. The costs of the equipment and supplies for the intervention, such as the touch screen, will be obtained from the research team and facility. We will also estimate the equipment costs associated with the control group and usual care provided at the facilities to provide comparison groups for the BIA. In addition to equipment and supplies, we will also estimate the staff time associated with the intervention and usual care. To obtain estimates of staff time for both

the discharge assistant and clinical teams, we will include questions about time when collecting implementation data. We will then estimate wages based on staff positions using data obtained from the facility. The economic analyses for Aim 3 will primarily consist of descriptive statistics. Using the estimates of costs of supplies, equipment, and staff time and the potential savings that result from decreased healthcare costs related to CHF and COPD, we will calculate the budget impact of implementing the intervention from the perspective of the facility. We will follow the guidelines outlined for best practices in BIA. We will create tables to describe the assumptions of our inputs and outputs, and perform sensitivity analyses to examine how changing the assumptions of the model impact the potential costs for the facility. To compare patient costs in the pre- and post-periods for the intervention and control groups, we will use GLM (generalized linear models) that accounts for the skewness in distribution of costs, and we will calculate 95% confidence intervals around differences in costs using bias corrected accelerated bootstrapping. Because there are potential issues of bias and precision, we will employ checks to select a model that is consistent and robust in the face of the skewness that is characteristic of healthcare costs.

4.0 Human Subjects

4.1 General Characteristics

Pre-Clinical Trial Activity – Beta Testing (Bedford Activity):
We are interested in understanding the usability experiences of Veterans with CHF and COPD. Thus, ten Veterans (five with CHF and five with COPD) will be recruited for interviews. Beta testing of the technology intervention components (relational agent tablet, automated text messages). This is not a treatment study; we are simply gathering feedback on the technology for their refinement prior to the larger pilot and subsequent clinical trial.

Pre-Trial Clinical Team Site Visit Semi-Structured Interviews (Bedford Activity):
We are interested in gathering input from clinical staff to inform the design and rollout of the intervention we are testing in our clinical trial. As such, we are gathering that input through interviews conducted as part of site visits at three trial sites.

Clinical Trial Activity (Boston, Palo Alto, Hines, Iowa City):
For Aim 2, our goal is to recruit 600 Veterans from among 1,913 with COPD/CHF as primary diagnosis and then expand to those within the total pool of 19,128 who have secondary diagnoses of CHF/COPD at the four study sites (Boston, Iowa City, Hines, Palo Alto).

Post-Clinical Trial Data Analysis:
For our formative evaluation (Aim 3), we will conduct semi-structured interviews with clinical leadership and inpatient clinical teams at three sites (Boston, Iowa City, Palo Alto). Site visits (by the PI (Hogan and project staff Richardson) will be organized and scheduled.

We will work with the discharge assistants and site PIs in advance of each visit to compile a list of inpatient clinical team members and other key informants (e.g., quality improvement officers). Recruitment of other clinical staff and key informants will proceed through an accumulative or "snowball" sampling strategy in the course of the interviews. Recruitment will continue until 1) there is redundancy in referrals and 2) we have sufficient data to support our implementation goals. We plan to recruit 12-15 participants from each site. All interviews will be one-on-one, semi-structured, and audio-recorded, lasting about 30 minutes. In conjunction with the start of each interview, participants will be asked to complete a short questionnaire to document their professional background, training, and work experience. Interview topic areas addressed will include current care transition practices, programs, and related interventions at the facility, use of technology to support care processes, characteristics of the clinical environment and corresponding implications for implementing novel, technology-based interventions, and pros and cons of using the kinds of technology specific to the Annie intervention to interact with older patients. All Aim 3 data will be analyzed at both ENRM VA and Hines VAMC.

The patients we are recruiting are in-hospital CHF and COPD patients. For sick patients with these conditions, rehospitalization is a common occurrence, especially within 30 days of leaving the hospital. The intervention that we have designed and are testing in this study is intended to help Veterans with CHF and COPD take better care of themselves post-discharge, and to reduce hospital readmissions. For these reasons, in this study, we consider rehospitalization a serious but anticipated adverse event that will be reported at each annual IRB continuing review and DSMB report as required.

We will not note hospital readmissions in patient charts as an adverse event since participants are being re-admitted by their physician. If the admission is unrelated to the research procedures, a research progress note about their readmission would not be useful for subject's clinical care.

Serious and unanticipated adverse events such as data breach or death will continue to be reported to IRB immediately.

4.2 Inclusion of Vulnerable Subjects and Special Populations

Participants from the four sites will be identified through daily census lists of hospital units. Our primary inclusion criteria are that Veterans have to have a diagnosis of CHF or COPD, be admitted to a general medical service and be able and willing to engage with the touchscreen. For the trial, patients will also be required to have access to a text-enabled cellular phone to receive the post-discharge text messages. Enrollment begins with the person facilitating enrollment initiating contact with the patient in their hospital room (most rooms are private rooms, and we will limit recruitment to patients in these rooms). The person facilitating enrollment at each site over the total 24 month enrollment period will be our "discharge assistants" who play the role of a centralized discharge facilitator and are funded by the grant. Consent and randomization will again follow protocols from Aim 1

Sub-Aim A. Randomization will be stratified by condition (CHF or COPD) to assure balance on this key variable. As all patients receive some intervention (active control or virtual nurse), they will remain blinded to group assignment. After discharge, patients will be re-contacted by study personnel at seven and 30 days to conduct follow-up assessments as detailed in D.3 (Aim 3).

Children are not included.

The research topic is focused on adult veterans hospitalized for congestive heart failure and/or chronic obstructive pulmonary disease, which may include women or minorities. We feel it is important to ensure adequate representation of women and minorities in this study. As such, we propose to oversample minorities with a goal of filling 20% of the sample. We will also prioritize recruitment of women Veterans into the study; recognizing that many women Veterans are younger and as such, may be less likely to have CHF or COPD diagnoses.

The clinical leadership and inpatient clinical team members may also include women, pregnant women, and minorities, but not children.

4.3 Inclusion of Incompetent Subjects

We will not enroll incompetent subjects. We will not enroll individuals who lack decision making capacity.

4.4 Inclusion/Exclusion Criteria

At each site, participants will be identified through daily census lists of hospital units. Our primary inclusion criteria are that Veterans have to have a diagnosis of CHF or COPD, be admitted to a general medical service, and be able and willing to engage with the touchscreen (control and intervention described below). Enrollment begins with the person facilitating enrollment initiates contact with the patient in their hospital room (most rooms are private rooms, and we will limit recruitment to patients in these rooms). In past trials, Dr. Houston has developed protocols for technology-assisted consent and randomization. These procedures are valuable as the work of consent shared with the technology and documentation is automated; also, the person facilitating enrollment is blind to random group assignment until after the computer-generated randomization occurs.

4.5 Recruitment Procedures

For beta testing at VA Bedford:

We will identify patients with CHF and COPD through chart reviews and with the help of physician researchers. Ten participants will be asked to test the relational agent (Group 1) and participants will be asked to test the text messages (Group 2).

We will identify eligible patients via chart review and then reach out to them via mailed letter that explains that we are recruiting patients to help provide feedback on the components of an intervention for patients with CHF/COPD. If they are interested, please call us. There is

an option to opt out of the study by calling a member of our research team. In the recruitment letter, we tell patients if they do not opt out within 10 days, they will be contacted by a member of the research team. If we reach our sample size target and no longer need to solicit further participation, we will follow up with the Veterans who we sent letters but who have not yet participated to alert them that enrollment is complete. We will send a letter to Veterans to let them know that recruitment has closed. We also have the option to identify eligible patients through VA's support Service Center (VSSC) reports: https://vssc.med.va.gov/ which provides data within its stewardship to established internal VA organizations/program offices for the purpose of health care delivery analysis and evaluation. We have made this note in the HIPAA waiver request as well. We will secure any necessary approvals to use the VSSC reports before doing so.

In addition to mailed letters as described above, we will work with physician researchers at Bedford and members of their clinical teams to hand flyers to patients who are being seen for appointments at Bedford and to let them know that they may be eligible to participate in the study and could do so the same day, while they are on the Bedford campus, if they are interested. This approach reduces the burden on the patient having to make an additional trip back to the Bedford campus to complete the study activities. We will ask the physician researchers and their clinical staff to introduce the study in a very limited and unbiased manner so as to avoid the appearance of coercion. We will ask them to say the following (which may be paraphrased slightly): "There is a VA-funded research project underway that aims to improve Veterans' experience with hospital discharge processes. You may be eligible to participate. If you are interested, you may call the telephone number on this flyer while you are here on campus to get more information or participate today. In this way, clinical staff are not recruiting patients or pressuring patients to participate.

For Site Visits Conducted by Study Team:

The study team will conduct semi-structured interviews at three trial sites with clinical staff as part of site visits. These site visits will be led by the PI, Dr. Hogan, and will be organized and scheduled by local study staff. We will work with the discharge assistants and site PIs in advance of each visit to compile a list of inpatient clinical staff and other key informants (e.g., quality improvement officers). Recruitment of other clinical staff and key informants will proceed through an accumulative or "snowball" sampling strategy in the course of the interviews. The discharge assistants will keep track of scheduled interviews in an encrypted excel file. Recruitment will continue until 1) there is redundancy in referrals and 2) we have sufficient data to support our implementation goals. We plan to recruit 12-15 clinical participants from each site. All interviews will be conducted under the approval of the Bedford study site, using Bedford consent forms, and will be one-on-one, semi-structured, and audio-recorded, lasting about 30 minutes. At the start of each interview, clinician participants will be asked to complete a short questionnaire to document their professional background, training, and work experience. Interview topic areas addressed will include current care transition practices, programs, and related interventions at the facility, use of technology to support care processes, characteristics of the clinical environment and corresponding implications for

implementing novel, technology-based interventions, and pros and cons of using the kinds of technology specific to the Annie intervention to interact with older patients. These procedures will *not* be conducted at the Bedford ENRM VA Hospital, but falls under the Bedford IRB.

For Beta Testing at Bedford:

We will identify patients with CHF and COPD through chart reviews and with the help of physician researchers and their clinical staff. Ten participants will be recruited to test the relational agent (Group 1) and ten participants will be recruited to test the text messages (Group 2).

For the clinical trial at Boston, Palo Alto, Hines, Iowa City:

For Aim 2, our goal is to recruit 600 Veterans from among 1,913 with COPD/CHF as primary diagnosis and then expand to those within the total pool of 19,128 who have secondary diagnoses of CHF/COPD at the four study sites (Boston, Hines, Iowa City, Palo Alto). Participants will be recruited at each study site (Boston, Iowa City, Hines, Palo Alto). Using the national sample of Veterans actively receiving VHA services available in the Corporate Data Warehouse, nationally, in 2013, there were over 435,700 Veterans with a diagnosis of CHF, and over 73,000 of them had at least one admission to a VHA facility (as primary diagnosis or secondary). Similarly, in 2013, there were over 789,500 Veterans with a diagnosis of COPD, and over 151,300 of them had an admission to a VHA facility. Thirty-day readmission rates for Veterans with CHF and COPD vary, but are in general higher than national averages. Based on statistics from the VHA Support Service Center (Inpatient Evaluation Center (IPEC)) Reports, there were a total of 1,147 Admissions for CHF, and 765 for COPD in 2013 (approximately 10% of all admissions). We will prioritize recruitment of patients with a primary admission diagnosis of CHF/COPD. If recruitment is falling below goal, we will also include patients with a secondary diagnosis of CHF/COPD admitted on general medical services. Thus, our goal is to recruit 600 Veterans from among 1,913 with COPD/CHF as primary diagnosis and then expand to those within the total pool of 19,128 who have secondary diagnoses of CHF/COPD at the four study sites.

Post-Clinical Trial Data Analysis:

For our formative evaluation (Aim 3), we will conduct semi-structured interviews with clinical staff at our study sites. Interviews will be organized and scheduled by the discharge assistants. We will work with the discharge assistants and site PIs in advance of each visit to compile a list of inpatient clinical staff and other key informants (e.g., quality improvement officers). The discharge assistants will identify appropriate participants. Recruitment of other clinical staff and key informants will proceed through an accumulative or "snowball" sampling strategy in the course of the interviews. Recruitment will continue until 1) there is redundancy in referrals and 2) we have sufficient data to support our implementation goals. We plan to recruit 12-15 participants from each site. All interviews will be conducted under the approval of the Bedford IRB, using Bedford

consent forms, will be one-on-one, semi-structured, and audio-recorded, lasting about 30 minutes. In conjunction with the start of each interview, participants will be asked to discuss their professional background, training, and work experience. Interview topic areas addressed will include current care transition practices, programs, and related interventions at the facility, use of technology to support care processes, characteristics of the clinical environment and corresponding implications for implementing novel, technology-based interventions, and pros and cons of using the kinds of technology specific to the Annie intervention to interact with older patients. All Aim 3 data will be analyzed at both ENRM VA and Hines VAMC.

4.5.1 Subject Identification and Pre-Enrollment Screening:

For the beta testing (Bedford):
We are interested in understanding the usability experiences of Veterans with CHF and COPD. We will identify patients with CHF and COPD through chart reviews and with the help of physician researchers and their clinical staff. Ten participants will be recruited to test the relational agent (Group 1) and ten participants will be recruited to test the text messages (Group 2).

For the clinical trial (Boston, Palo Alto, Hines, Iowa City):
For Aim 2, our goal is to recruit 600 Veterans across the four sites—with COPD/CHF as primary diagnosis and then expand to those within the total pool to those who have secondary diagnoses of CHF/COPD at the four study sites.

To understand provider attitudes toward and perceptions of our care transition intervention, and the impact that the inpatient touchscreen and outpatient text messaging intervention components had on communication between providers and Veterans, we will identify providers who treated patients enrolled in the trial. Sampling will be done using CDW data to identify providers at our study sites who had outpatient encounters with Veterans enrolled in the trial for treatment related to CHF and/or COPD. The identified providers will receive an initial email with a link to a brief REDCap survey. After approximately 1-week, these providers will receive an email reminder to complete the brief REDCap survey if they have not done so already. Initially, the vision was to gather provider feedback about our intervention through interviews and possible post-trial site visits; however, due to the COVID-19 pandemic, we cannot travel for site visits and we want to minimize the potential burden that this data collection presents to providers as much as possible. Our brief REDCap survey should take approximately 5 minutes for providers to complete.

4.5.1a HIPAA Authorization for Recruitment and/or Screening:

For the Bedford beta testing we are requesting a waiver of authorization for recruitment and screening. We will access the following information from VA Health Records: SSNs (last four only), diagnoses, demographic information such as

name, age, race, addresses and phone numbers. PHI will be used for study recruitment.

4.5.1b Consent for Recruitment and/or Screening:
For the Bedford beta testing:
We are requesting a waiver of consent and HIPAA authorization for conducting chart reviews for patient screening and gathering contact information.

For beta testing and trial:
We will be conducting chart reviews for patient screening and gathering contact information. We will continue to monitor charts for discharge and possible readmission dates and follow up. Post-intervention, a second chart review will be conducted for all enrolled participants.

As in the beta testing, patients from the four sites will be randomized to the full Annie intervention (onscreen inpatient and texting outpatient), or the active comparison control. Informed consent will explain to the patients that they will receive one of two interventions to support their transition back to home. For each study site (Boston, Iowa City, Hines, Palo Alto), the IRB-approved informed consent and HIPAA waiver will be read aloud to patients. After this review, the enrollment facilitator (discharge assistant) will obtain a signature on paper copies of the consent and waiver. Patients will then agree to participate on-screen and complete a brief baseline survey.

4.5.2 Enrollment: The site discharge assistants at each site will enroll participants.

As indicated in the informed consent, a research note will be included in the patient's chart specifying they are involved in our study. The research note will include elements as required by Appendix U in the IRB SOP including: start date, duration of enrollment, study staff contact information, information about the study, risks, and consent.

When access to patient health records is no longer required for a study, the study has been completed, or when authorization is revoked, the investigator or designee, must notify the facility HIM program manager and, if applicable, the ISO (in accordance with VHA Handbook 1907.01).

For the site visits and clinical trial only:
Clinical interviews will occur pre-post intervention.

4.5.2a HIPAA Authorization:

For beta testing, participants will sign the HIPAA authorization. We will protect the identifier, and destroy the identifiers at the earliest opportunity (which for the VA at the current time means that retention of all data is mandated by the VA records control schedule, and must be retained until disposition instructions are approved by the National Archives and Records Administration and are published in the VHA's Records Control Schedule (RCS 10-1)).
PHI will not be used and or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use of disclosure of the requested information would be permitted by the Privacy Rule.

For the clinical trial:
Each site will request HIPPA authorization for their study activities. We will protect the identifier, and destroy the identifiers at the earliest opportunity (which for the VA at the current time means that retention of all data is mandated by the VA records control schedule, and must be retained until disposition instructions are approved by the National Archives and Records Administration and are published in the VHA's Records Control Schedule (RCS 10-1)).
PHI will not be used and or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use of disclosure of the requested information would be permitted by the Privacy Rule.
Clinicians will not complete a HIPPA authorization.

4.5.2b Informed Consent:

For the Bedford beta testing:
The IRB-approved informed consent and HIPAA authorization will be read aloud to patients. After this review, the research team member will obtain a signature on paper copies of these documents (in person at VA Bedford).

For the trial:
The IRB-approved informed consent and HIPAA waiver will be viewed on-screen and will be read aloud to patients using the speakers on the tablet. After this review, the enrollment facilitator (discharge assistant) will obtain a signature on paper copies of the consent and waiver. Patients will then agree to participate on-screen and complete a brief baseline survey. The informed consent process will be completed prior to initiation of the study procedures. Each site will maintain a master list of all subjects from whom informed consent has been obtained. The discharge assistant will

review the consent documents with the patient and provide ample time to address questions or concerns.
Clinicians will also be presented an informed consent document in a similar manner.

4.6 Risk/Benefit Ratio

4.6.1 Potential Risks and Methods to be Used to Minimize Risks:

The risks of the study are minimal. Risks to participants relate mostly to misinterpretation of what is research and loss of confidentiality. The major risk is the accidental disclosure of information; however, every precaution will be taken to prevent this from occurring. Our study team has had direct experience with data loss, and we have developed a strong culture of secure, detailed operating procedures, and are hyper vigilant of protection of confidential data. In no way will individual participant data be released to the public or cited in a publication.

All data will be coded with a patient code (for example, patient001). Any hardcopy files will be stored in locked file cabinets at each respective site. A file stored separately from the data will contain participant identifiers and codes. All recordings will be stored on a secure server located at each site. Data for analyses will be stored at the Bedford ENRM VA Hospital behind the VA firewall. In an access-restricted folder on network servers maintained by a dedicated CHOIR IT specialist. Server v01.med.va.gov Q:\DATA\Hogan TACT CHF COPD IIR. All computers are password protected and all computers on which data analysis will be done are encrypted using VA authorized encryption software. Study personnel including investigators, project coordinator, research assistants, discharge assistants, and data analyst will have access to data/codes. All recordings will be transcribed. Transcription will be done by a certified transcription service which meets all VA security standards.

There may be some stress involved in patients describing their care transition experience, learning how to use the Virtual Nurse, and for the healthcare providers to be observed in their care transition support activities, but we will emphasize that this participation is voluntary.

Any hospitalizations or deaths discovered by the research team will be promptly reported to IRB with an assessment of whether any study procedures may have contributed to these outcomes.

4.6.2 Data and Safety Management Plan:

4.6.2.1 Data Security

The principal investigator will be responsible for monitoring the safety and efficacy of the study, executing the data and safety monitoring plan, and complying with the reporting requirements. The site PI's will report participant sociodemographic

characteristics, expected versus actual recruitment rates, any quality assurance or regulatory issues that occurred during the past year, summary of adverse events, and any actions or changes with respect to the protocol directly to the PI.

In no way will individual participant data be released to the public or cited in a publication. All data will be coded with a patient code (for example, patient001). Any hardcopy files will be stored in locked file cabinets at each respective site. A file stored separately from the data will contain participant identifiers and codes. All recordings will be stored on a secure server located at each site. Digital data for analyses will be stored at the Bedford ENRM VA Hospital behind the VA firewall. In an access-restricted folder on network servers maintained by a dedicated CHOIR IT specialist. All computers are password protected and all computers on which data analysis will be done are encrypted using VA authorized encryption software. Study personnel including investigators, project coordinator, research assistants, discharge assistants, and data analyst will have access to data/codes. All recordings will be transcribed. Transcription will be done by a certified transcription service which meets all VA security standards.

4.6.2.2 Data Safety Monitoring

All study data containing PII or PHI in electronic format or in paper format will be stored on VA equipment and will be maintained on password protected and encrypted computers, behind locked doors, in a secure VA building. No data will be stored outside the VA.

Study data will be kept in accordance with the department of veterans affairs record control schedule 10-1 (RCS 10-1). The PI in conjunction with the VA ISO, and in accordance with VA policy, will ensure that upon completion of the research project, study data containing sensitive, confidential information will be returned to the VA, sanitized and removed from all servers, desktops, removable storage devices, etc.

Paper copies will be stored in a locked file cabinet of each PI's locked VA office. Paper copies of research data will be sent to Bedford via common carrier or transported by Bedford staff while on site visits; if it is electronic (SharePoint and/or shared VA Drive) will be sent via delivery service with a chain of custody per VA Handbook 6500, Appendix D, AC-19 and VA Directive 6609). Removal of access to research study data will be accomplished for study personnel when they are no longer part of the research team per VA Handbook 6500, Appendix D, AC-2.

The patients we are recruiting are in-hospital CHF and COPD patients. For sick patients with these conditions, rehospitalization is a common occurrence, especially within 30 days of leaving the hospital. The intervention that we have designed and

are testing in this study is intended to help Veterans with CHF and COPD take better care of themselves post-discharge, and to reduce hospital readmissions. For these reasons, in this study, we consider rehospitalization a serious but anticipated adverse event that will be reported at each annual IRB continuing review and DSMB report as required.

We will not note hospital readmissions in patient charts as an adverse event since participants are being re-admitted by their physician. If the admission is unrelated to the research procedures, a research progress note about their readmission would not be useful for subject's clinical care.

Serious and unanticipated adverse events such as data breach or death will continue to be reported to IRB immediately.

Each site has a medically trained staff member monitoring for SAE's. In the event of an SAE, the site IRB, as well as the project PI (Hogan and Bedford) will be notified.

4.6.3 Potential Benefits:

The major benefit to patients, caregivers and healthcare providers is improved care transition support, improved communication between patients, caregivers and providers, potentially decreased rehospitalizations and medication discrepancies, and improved patient/caregiver quality of life through increased care transition self-efficacy.

The project has the potential to improve the care transition process which would likely provide direct health benefits to the participant.

The care transition support program is a practical intervention that is highly likely to be disseminated. Our project will test this intervention and will result in advancements in our understanding of how care transition support can best be implemented in the VA.

4.6.4 Alternative Procedures:

For beta testing:
This is not a treatment portion of the study. The alternative is not to participate.

For the trial
The discharge procedure may vary from VA to VA; it is referred to as "normal care" and includes the VA's best efforts to provide high quality care to Veterans. Practices usually include one on one medical provider to patient education, discharge planning, and follow up. These procedures will not be altered as a result of this study, only augmented with additional education and discharge follow-up.

4.7 Costs and Payments

Veterans who participate in the study will be given a $30 incentive for participation as a way to compensate them for their time. Receiving and responding to text messages may result in charges billed by the phone company for some participants if they do not have a cellular phone plan that includes text messaging. In such cases, participants will be reimbursed for text messaging costs with an additional $5, $10 or $15 gift card depending on the costs incurred.

4.8 Providing for Reuse of Data

For the beta testing:
Data will not be stored for reuse.

For the trial:
We will submit an amendment to set up a data repository. The data will be stored in a data repository, a new data repository being set up here at the ENRM VA Hospital, for future research studies pertaining to care transition intervention and implementation. All data will be stored and maintained according to VA regulations and only investigators approved through the data repository committee will have access to this data. Any future use of the data will be reviewed and approved by this committee. The creation and management of this data repository will be approved by the ENRM VA Hospital IRB and Research and Development Committee before any of the data from this study will be stored in it for future use. Once the Data Repository has been approved, an amendment to this project will be submitted to store the data in the data repository.

4.9 Creation of a Tissue Bank

Not Applicable

5.0 Resources

The activities occurring at Bedford ENRM VA Hospital will capitalize on the resources at the Center for Healthcare Organization and Implementation Research (CHOIR) located at the Bedford ENRM VA Hospital. CHOIR is a VA HSR&D Center of Innovation, with locations at the Bedford ENRM VA Hospital and the VA Boston Healthcare System. CHOIR has a staff of over 72 core investigators, including 34 principal investigators with expertise in fields including organizational behavior, implementation science, treatment decision-making, medical informatics, patient safety, quality measurement, and qualitative methods. CHOIR's Bedford facilities include over 20,000 square feet of office space, providing adequate space research investigators, support staff, and equipment. Mail (including UPS), telephone, fax, and duplicating equipment are provided. CHOIR provides the basic computer and administrative support for this project, with high-speed internet and email access as well as productivity and statistical software. CHOIR maintains a local computer network in support of its research projects with high-speed network switches for interconnecting workstations with servers and data files and over 5 terabytes of secured memory.

6.0 Collaborations

Boston VAMC Site:

CHOIR is a dual location center encompassing Boston VAMC. The Boston VAMC environment is similar to that of the Bedford VAMC. The Boston VAMC Site PI, Dr. Steven Simon, is also the Chief of General Internal Medicine in the VA Boston Healthcare System and will be able to help ensure that our team has the resources we need at the Boston facility during the implementation and evaluation phases of our work. A site discharge assistant will also be available to train teams on the intervention and agent and assist throughout the intervention. Boston VA Healthcare System is the largest consolidated facility in VISN 1, encompasses 3 main campuses and 6 outpatient clinics within a 40-mile radius of the greater Boston area. The consolidated facility consists of the Jamaica Plain Campus; the West Roxbury Campus; and the Brockton Campus. In addition to the 3 main medical centers, 4 Community Based Outpatient Clinics (CBOCs) located in Framingham, Lowell, Quincy, and Causeway Street (Boston) make up the VA Boston Healthcare System (VA BHS). VA BHS serves as a national Research and Development center for medical research and is a major tertiary care center for the VA New England Healthcare System Veterans Integrated Service Network (VISN). Academic affiliations include University of Massachusetts Medical School, Harvard Medical School, Boston University Medical School, Tufts University School of Medicine as well as affiliations with 7 other major medical facilities in the greater Boston area.

Iowa City VAMC Site:

The Iowa City VAMC environment is similar to that of the Bedford VAMC. The Iowa City VAMC Site PI, Dr. Bonnie Wakefield, has expertise in working with and leading interdisciplinary teams, designing interventions, recruiting patients with chronic illness, collecting and analyzing data using both standard instruments and interviews (in person and audio-recorded), supervising a variety of research personnel, and disseminating findings through publication and presentations. She serves as the Clinical Coordinator for the current VA eHealth Quality Enhancement Research Initiative. A site discharge assistant will also be available to train teams on the intervention and assist throughout the intervention.

The research staff will be housed in dedicated research space within the VA Health Services Research and Development (HSR&D) Research Enhancement Award Program (REAP) (Center for Comprehensive Access & Delivery Research and Evaluation (CADRE) at the ICVAHSC. CADRE occupies roughly 10,800 square feet of space including 32 private, 13 semi-private offices, 30 work stations, and 2 conference rooms. The ICVAHSC houses the VHA Office of Rural Health, Veteran's Rural Health Resource Center – Central Region and the VISN 23 Patient Aligned Care Team (PACT) Demonstration Lab. The ICVAHSC is situated in the Health Science Center of the University of Iowa, which includes the UI Colleges of Medicine, Dentistry, Nursing, Public Health, and Pharmacy, the University Hospitals and Clinics, and the Hardin Health Sciences Library.

Palo Alto VAMC Site:

The Palo Alto VAMC environment is similar to that of the Bedford VAMC. The Palo Alto VAMC Site PI, Dr. Paul Heidenreich, is the Director of the Chronic Heart Failure (CHF) QUERI

and will be able to help ensure that our team has the resources we need at the Palo Alto facility during the implementation and evaluation phases of our work. A site discharge assistant will also be available to train teams on the intervention and agent and assist throughout the intervention. Palo Alto project personnel will be housed in office space provided for the Center for Innovation to Implementation (Ci2i), a VA HSR&D Center of Innovation, which is housed in Building 324 at the Menlo Park Division; this newly renovated building is expected to provide adequate space and other resources for the conduct of this research.

Due to the range of projects, numbers of experienced investigators, and supportive research climate, Ci2i researchers are able to identify, recruit, and retain highly qualified research health science specialists (RHSSs). Ci2i core investigators currently support or supervise several RHSSs who are experienced in project management, including IRB procedures, participant interviews, data management, and data analysis. These individuals serve as resources for one another and can consult with other co-located research staff with statistical expertise.

Ci2i provides access to state-of-the-art computer capabilities, including individual workstations, in-house technical computer support personnel, telephones, faxes, and secure servers with ample capacity to handle large databases, secure access to project directories, and storage for Ci2i projects. The secure servers also store standard statistical and data transfer software and copies of most secondary VA data sets. The facility provides daily incremental and monthly full system back-ups, as well as state-of-the-art security measures, such as a locked server room with alarms. Ci2i facilitates program requirements for reliability, rapid-paced communication, online database retrieval, electronic document transfer, and high-quality graphics presentations.

Hines VAMC Site and Staff:

Edward Hines, Jr. VA Hospital, located 12 miles west of downtown Chicago on a 147-acre campus, offers primary, extended and specialty care and serves as a tertiary care referral center for VISN 12. Specialized clinical programs include Blind Rehabilitation, Spinal Cord Injury, Neurosurgery, Radiation Therapy and Cardiovascular Surgery. The hospital also serves as the VISN 12 southern tier hub for pathology, radiology, radiation therapy, human resource management and fiscal services. Hines VAH currently operates 483 beds and six community based outpatient clinics in Elgin, Kankakee, Oak Lawn, Aurora, LaSalle, and Joliet. More than 700,000 patient visits occurred in fiscal year 2014 providing care to more than 57,000 veterans, primarily from Cook, DuPage and Will counties.

Dr. Bridget Smith was the co-director of SCI QUERI and has extensive experience with mixedmethods projects. Edward Hines, Jr. VA Hospital, located 12 miles west of downtown Chicago on a 147-acre campus, offers primary, extended and specialty care and serves as a tertiary care referral center for VISN 12. Dr. Smith will also work closely with the site discharge assistant and clinical staff throughout the training and implementation phases of this project.

Northeastern University: See attached MOU

Northeastern's College of Computer and Information Science remains a national leader in education and research innovation. Education and research focus on providing the knowledge and perspective needed in an increasingly complex world. Educational programs combine computing with an important application domain, such as health or security. Research both

advances computing and contributes to resolving major societal challenges. The college's programs, faculty, and research are developing international prominence in four significant areas: cyber security, personal health informatics, network science, and software reliability. Faculty work individually and with researchers across Northeastern to address how computing can contribute to improving the quality and cost of health care, understanding the impact of social networks, and increasing the reliability and security of the systems and networks people turn to every day. The college also boasts one of the country's top programming languages groups and has strong research programs in software development, algorithms and theory, formal methods, networks, systems, databases, information retrieval and data mining, human–computer interaction, artificial intelligence, and robotics. The college offers a small, close-knit community and the resources of a large, urban university. An award-winning building with state-of-the-art classrooms and labs, wired and wireless networks, and thoughtfully designed open meeting space enhances learning and research.

7.0 Qualifications of the Investigators

Timothy Hogan, PhD, Principal Investigator: Dr. Hogan is the Implementation Research Coordinator (IRC) for the eHealth Quality Enhancement Research Initiative (QUERI), investigator at the Center for Healthcare Organization and Implementation Research (CHOIR) and Assistant Professor within the Division of Health Informatics and Implementation Science at the University of Massachusetts Medical School. Dr. Hogan's PhD is in Information Science and he completed a VA HSR&D postdoctoral fellowship in Health Services Research. His expertise lies in the areas of consumer health informatics, health communication, and research methods, specifically primary data collection and analysis techniques and the application of mixed methods in implementation research. He has worked on numerous projects to implement technology-assisted interventions among patients with complex, chronic healthcare needs, including Veterans with spinal cord injury and co-morbid chronic conditions. He was principal investigator on a previous RRP focused on implementing use of My Health*e*Vet in the VA Spinal Cord Injury System of Care and is principal investigator on a current RRP to design and implement a toolkit to support use of the Blue Button feature of My Health*e*Vet among patient-aligned care team members.

Thomas Houston, MD MPH, Co-Principal Investigator: Dr. Houston is a 5/8 VA physician scientist and Director of the eHealth QUERI centered in Bedford, MA. He is a senior scientist at CHOIR and the Chief of the Division of Health Informatics and Implementation Science within the Department of Quantitative Health Sciences, University of Massachusetts Medical School. Dr. Houston has gained national recognition for his health informatics research with a specific focus on patient-centered informatics. His prior work has included research on doctor-patient electronic communication, and web-delivered interventions for behavior change for patients and providers. Dr. Houston was also co-principal investigator of a previous study funded by the Agency for Healthcare Research and Quality (AHRQ) and focused on care transitions for chronically ill patients. He will bring all of this expertise to the current proposal and work in close collaboration with Dr. Hogan to lead the project.

Stephanie Shimada, PhD, Co-Investigator: Dr. Shimada is a current QUERI-supported VA Career Development Awardee at the Center for Healthcare Organization and Implementation Research (CHOIR) in Bedford, MA and an Assistant Professor in the Department of Health Policy and Management at the Boston University School of Public Health. She was the first Implementation Research Coordinator for the eHealth QUERI. Dr. Shimada's work has focused on quality measurement and patient safety, disparities in healthcare, and on understanding the decisions patients make as consumers of healthcare services. Her current Career Development Award focuses on the implementation and evaluation of patient-facing technologies in VA. She is currently conducting a national study of patient adoption of My Health*e*Vet and is engaged in several studies examining patient and provider experiences with secure messaging. Dr. Shimada has experience with qualitative methods including interviews and qualitative data analysis.

Keith McInnes, ScD, MS, Co-Investigator: Dr. McInnes is a VA Health Services Researcher and Research Assistant Professor at Boston University School of Public Health. He is a member of the MyHealth*e*Vet Performance Evaluation Committee and CHOIR's Public Health Communications Steering Committee. Prior to joining VA, he held positions at the Department of Health Care Policy, Harvard Medical School, and the Harvard Program in Refugee Trauma, at Massachusetts General Hospital. He was one of the developers of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Health Information Technology supplement. Dr. McInnes was the recipient of a 2005-2006 Packer Policy Fellowship at the University of Sydney, Australia and he is a current VA Career Development Awardee focusing on access to care and care quality among low-income and homeless veterans with HIV or hepatitis C. Current projects include a text messaging interventions with homeless veterans, and a qualitative exploration of the role of informal caregivers in the treatment process for veterans undergoing hepatitis C medication treatment. Dr. McInnes will provide conceptual and methodological guidance to the research team over the course of the project.

Edward Hines, Jr. VA Hospital VA Personnel: Bridget Smith, PhD, MPA, Co-Investigator. Dr. Smith is Co-Director of the Spinal Cord Injury QUERI and a Research Health Scientist at the Center of Innovation for Complex Chronic Healthcare (CINCCH) at the Hines VA. She is also the lead economist for the eHealth QUERI. Dr. Smith is principal investigator on several VA HSR&D QUERI-funded projects that inform the implementation aspects of this proposal, including two recent RRPs examining the implementation of telehealth applications to support access to care among Veterans with complex, chronic healthcare needs. She has also conducted budget impact analyses for other technology-assisted interventions and patient-facing technologies of interest to the eHealth QUERI and will bring that expertise to this project. She will lead the budget impact analysis included in aim 3. Dr. Smith will also work closely with the site discharge assistant and clinical staff throughout the training and implementation phases of this project.

Connected Health Program Office, Office of Informatics and Analytics: Neil Evans, MD, Co-Director of the Connected Health Program Office, Office of Informatics and Analytics, and the Associate Chief of Staff, Informatics at the Washington DC VA Medical Center, Co-

Investigator. The Connected Health Program Office seeks to improve the delivery of healthcare services to Veterans and their family caregivers by increasing access, fostering continuity, and promoting patient empowerment through eHealth technologies. The Connected Health Office oversees the enterprise-wide digital health strategies of VA and serve as the eHealth QUERI's primary operational partner. Connected Health is rolling out a computer tailored health communication (CTHC) system (HealtheDialog) that will support the automated exchange of tailored SMS text messages with Veterans in an effort to improve disease management and patient care outcomes. Dr. Evans will be instrumental to keeping the research team current on these initiatives.

Iowa City VAMC Personnel: Bonnie J Wakefield, PhD, RN, FAAN, Site PI and Co-Investigator. Dr. Wakefield is one of two clinical coordinators for the eHealth QUERI, an investigator at the Comprehensive Access and Deliver Research and Evaluation (CADRE) Center, as well as an Associate Research Professor at the Sinclair School of Nursing, University of Missouri. Dr. Wakefield's research focuses on design and evaluation of e-health communication technologies to improve access and quality care for chronically ill Veterans. Along with providing conceptual and methodological guidance to the research team over the course of the project, Dr. Wakefield will also advise on intervention training plans at the project sites, working closely with Dr. Smalls to do so. Dr. Wakefield will function as the site PI for the Iowa City VAMC and work closely with the site discharge assistant. Dr. Kaboli will assist Dr. Wakefield.

Iowa City VAMC Personnel: Peter J. Kaboli, MD, MS, FACP, FHM, Co-Investigator and Site PI. Dr. Kaboli is the former Director of the Veterans Rural Health Resource Center-Central Region, a field office of the VA Office of Rural Health, and is now the Chief of Medicine at the Iowa City VAMC. Dr. Kaboli's research interests include rural health, inpatient medical care quality and organization, development of methods for measuring the appropriateness of medication prescribing, and the development of interventions to optimize treatment delivery and effectiveness in vulnerable segments of the Veteran population. Dr. Kaboli will function as an assistant site PI for the Iowa City VAMC and work closely with the site discharge assistant and Dr. Wakefield throughout the training and implementation phases of this project.

Palo Alto VAMC Personnel: Paul Heidenreich, MD, MS, Site PI. Dr. Heidenreich is a cardiologist and Director of the chronic heart failure (CHF) QUERI. Beyond his portfolio of research, Dr. Heidenreich has been serving in the role of content expert for the Connected Health Program Office, supporting their development and rollout of the HealtheDialog CTHC protocol for CHF. In addition to offering his clinical expertise in CHF and his broader knowledge of care transition interventions (e.g., VA's H2H Initiative) across VA, Dr. Heidenreich will function as the site PI for the Palo Alto VAMC. He will work closely with the site discharge assistant throughout the training and implementation phases of this project, and will offer his clinical and research expertise as necessary.

Boston VA Personnel: Steven R. Simon, MD, MPH, Site PI. Dr. Simon is a VA physicianscientist, one of two clinical coordinators for the eHealth QUERI, and the Chief of General Internal Medicine at VA Boston Healthcare System. Dr. Simon has an extensive portfolio of funded research examining the impact of health information technology on quality and safety, and has a current IIR examining the use of relational agent technology to support brief alcohol screening in VA primary care. He is pursuing this work with Dr. Timothy Bickmore – the leading authority in relational agent design and implementation. Dr. Simon will provide his expertise on the use of relational agent technology in VA care settings and will function as the site PI for the Boston VA. He will work closely with the site discharge assistant throughout the training and implementation phases of the project .He will donate 10% of his time.

Contracted: Timothy W. Bickmore, PhD, Co-Investigator. Dr. Bickmore is an Associate Professor in the College of Computer and Information Science at Northeastern University and a world-renowned expert on relational agent technology. Dr. Bickmore is also a co-investigator on Project Re-Engineered Discharge (RED), contributing his expertise in relational agents to the design of a virtual patient advocate to reduce ambulatory adverse drug events. Within VA, he is working closely with Dr. Steven Simon on a currently-funded IIR to design and test the effectiveness of a relational agent for brief alcohol screening among Veterans. In the current proposal, Dr. Bickmore will advise on the design and rollout of the Nurse Fox intervention, particularly the interactive touch screen and computerized personality that will comprise the pre-discharge segment of the intervention.

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Protocol Supplement for Multi-Site Studies Overseen by the Bedford IRB

The study **"A Technology-Assisted Care Transition Intervention for Veterans with Chronic Heart Failure or Chronic Obstructive Pulmonary Disease"** involves human research involving more than one engaged institution. Each institution is responsible for safeguarding the rights and welfare of human subjects entered at its site, and for complying with all applicable local, VA, and other Federal requirements.

Below are the methods used to achieve the responsibilities of **"Timothy P. Hogan"** the Principal Investigator of this Study.:

• All engaged participating sites must follow the most current version of the protocol, the most current version of the informed consent form, and the most current version of the HIPAA authorization. When documents become available, notification of study teams is achieved by doing the following:

"Dr. Hogan will be in touch with each site PI at monthly meetings, IRB updates will be a standing agenda item"

• All required approvals are obtained at each engaged participating site before the study is implemented at that site. This will be achieved by doing the following:

"Each site PI will obtain site IRB approval and notify Dr. Hogan"

• Dr. **"Hogan"** notifies the Director of any facility deemed not to be engaged in the research , but on whose premises research activities will take place, before initiating the study(when applicable). This will be achieved by doing the following:

"Each site PI will also be in touch with their site facility director"

• All amendments and modifications to the protocol, the informed consent form, and the HIPAA authorization must be communicated to the engaged participating sites.

"Dr. Hogan will be in touch with each site PI at monthly meetings, IRB updates will be a standing agenda item"
All required local facility approvals will be obtained before the amendment or modification is implemented. This will be achieved by doing the following:

"Each site PI will obtain site IRB approval and notify Dr. Hogan"

• All engaged participating sites will safeguard VA data as required by VA information security policies. This will be achieved by doing the following:

"All study materials will be secured behind a VA firewall and/or locked in a VA office and file cabinet"

• SAEs that have the potential to affect implementation of the study will be communicated to engaged participating sites. This will be achieved by doing the following:

"Each site PI will report SAEs directly to their site IRB as well as to Dr. Hogan who will report to Bedford IRB"

• Study events and interim results (if appropriate) are communicated regularly to engaged participating sites. This will be achieved by doing the following:

"Dr. Hogan will be in touch with each site PI at monthly meetings"

• LSls must conduct the study appropriately. This will be achieved by doing the PI/SC doing the following to ensure adequate monitoring:

"Each site PI will be in touch with their facility management and Dr. Hogan will be in touch with Bedford facility management"

• All non-compliance with the study protocol or applicable requirements must be reported in accordance with VHA Handbook 1058.01 and the VA Central IRS Table of Reporting Requirements. This will be achieved by doing the following:

"Each site PI will report issues directly to their site heads as well as to Dr. Hogan who will report to Bedford as appropriate"

• All local facility directors and LSls are notified when a multi-site study reaches the point that it no longer requires engagement of the local facility (e.g., all subsequent follow-up of subjects will be performed by the PI from another facility). This will be achieved by doing the following :

"Each site PI will be in touch with their facility management and Dr. Hogan will be in touch with Bedford facility management"