

## Cover Page

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**Study Title: My Recordable On-Demand Audio Discharge Instructions (MyROAD)**

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Note: American Greetings, a Cleveland based company, will provide cards for the intervention group with the pre-recorded messages.

## ABSTRACT

Non-adherence to the heart failure (HF) plan of care after hospital discharge has been associated with clinical outcomes, including the combined endpoint of all-cause mortality and rehospitalization for decompensated HF. Most patients are discharged with a complex set of instructions that include multiple medications (and differing medication administration plans), sodium restricted diet, fluid management actions (daily weight monitoring and in some cases, fluid restriction), monitoring signs and symptoms of HF, activity and exercise, and when to return for follow-up. At discharge, patients (and their families) may not understand that HF is chronic. Improvement in quality of life may be dependent on patients' acceptance of HF as a chronic, irreversible condition that requires self-care monitoring and behaviors (for example, becoming or staying physically active), even when they feel fine. To decrease the complexity of understanding HF, patients receive a HF handbook and a "zones" 1-page handout before discharge. In addition, they can watch multiple video clips of many HF topics and discuss HF self-care with the hospital healthcare team. However, patients may not read (or view) education materials due to health literacy issues, cognitive decline, eyesight issues, fatigue or depression. Patients may rely on lay (family) caregivers to understand self-care expectations and be active partners in care. Caregivers engaged in patients' care may not be present at discharge or may have preconceived or inaccurate ideas about HF self-care after discharge. A recorded message that could be repeatedly played by patients and caregivers might increase adherence to post-discharge self-care behaviors and 7-day follow-up appointments, and have clinical benefits related to a reduction in all-cause mortality and rehospitalization. The purposes of this randomized, controlled study are to examine the effects of use of a novel MyROAD (Recordable On-Demand Audio Discharge) card, given to patients at discharge. The aims of this single-blind, placebo-controlled study are to examine the effects of recorded messages that can be replayed post discharge (delivered via the MyROAD card) on (1) 45-, 90-, and 180-day *first occurrence* and (2) *time to first occurrence* of all-cause and HF-related hospitalization, ED visits and death/cardiac transplantation/ventricular assist device, (3) 45-day quality of life, symptoms, functional status and perceived adherence to activity recommendations, and (4) 7-day follow-up appointment with the healthcare provider assigned before discharge. A total of 1066 patients (968 + 10% attrition) with decompensated HF will be randomized to either usual care or usual care and receiving a MyROAD card at discharge.

## INTRODUCTION

Chronic heart failure (HF) is a costly diagnosis;<sup>1</sup> especially for patients who are hospitalized due to decompensation. Heart failure decompensation and hospitalization place patients at high risk for rehospitalization, exacerbating costs of care and potential penalties associated with the Patient Portability Affordable Care Act.<sup>2</sup>

Adherence to HF self-care maintenance (carrying out HF self-care behaviors recommended to patients with most etiologies of HF: limiting sodium intake per day, being active and exercising, managing fluids by daily weight monitoring and fluid restriction, monitoring for signs and symptoms of worsening HF, taking medications as ordered, and receiving follow-up care early after discharge) and management (calling a healthcare provider for new or worsening symptoms or taking actions to reduce sodium or fluid intake) behaviors were associated with improved clinical outcomes, including survival and fewer rehospitalizations.<sup>3-5</sup> Of note, when researchers studied 4 self-care behaviors in 830 patients with HF (weight monitoring, low sodium diet, fluid restriction and activity) at 30 days after hospital discharge, only 48% were adherent. At 18 months, all-cause mortality or HF rehospitalization was lower among patients who were adherent to all 4 behaviors versus 0 or 1, 2, or 3 behaviors.<sup>4</sup> Of behaviors, exercise was the most important in reaching the primary endpoint ( $p=0.002$ ), and when outcomes were analyzed independently, 18-month rehospitalization was significantly lower in patients who were adherent to the exercise expectations ( $p=0.007$ ).<sup>4</sup> Further, in a research study of nurses comfort in and frequency of providing HF self-care discharge education, activity behavior instructions ranked lowest in both comfort and frequency. Thus, patients may not receive activity instructions.<sup>6</sup> In a research study of patient's perceptions of activity and exercise, researchers found that patients did not understand activity and exercise expectations and generally, were sedentary.<sup>7</sup> Ultimately, activity behaviors after hospital discharge may be an important part of self-care that requires more discussion, to enhance adherence.

There are many reasons why patients are non-adherent to the HF plan of care. They may know what to do, but not how to incorporate change into their daily routine.<sup>8</sup> Patients may have impaired memory, cognitive decline, lack of social support,<sup>9-11</sup> have general or exertional fatigue,<sup>12</sup> be older, have polypharmacy, poor sleep and comorbid conditions,<sup>13</sup> and have cultural, socioeconomic, psychological, or physiological reasons.<sup>14</sup> In a study that assess factors associated with 7-day follow-up appointment adherence, researchers used medical record and Centers for Medicare and Medicaid billing data and found that greater distance from the doctor's office, black race, rural address, lower socioeconomic status and women were associated with non-adherence.<sup>15</sup> Further, patients' (and caregiver) acceptance of HF as a chronic condition that requires self-care actions, even when asymptomatic, may not be well understood; however, in one study, patients acceptance of HF was the only independent predictor of quality of life in the energy, pain, emotional reactions, sleep, social isolation and mobility domains.<sup>16</sup>

In addition to the many factors that may predict non-adherence to HF self-care, at hospital discharge, patients may be overwhelmed with materials and messages and may be unable to discern what self-care behaviors to focus on. Lay caregivers may not be present or may have misperceptions about self-care expectations. Repetition of messages is an age-old way to

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enhance understanding of communication.<sup>17</sup> However, it is unknown if a card with a standardized recordable messages specific to HF self-care, that can be replayed repeatedly after discharge, will enhance knowledge of expected self-care behaviors that leads to improved adherence, and improved clinical outcomes after discharge.

### Study Purposes

The purposes of this study are to test the effects of a novel card with recorded discharge instructions that can be replayed on-demand post-discharge in the home, called “My Recordable On-Demand Audio Discharge (MyROAD) Instructions” card.

The following outcomes will be assessed:

1. 45-, 90-, and 180-day *first occurrence* of post-discharge all-cause and HF hospitalization, emergency department [ED) visit, and death or cardiac transplantation/ ventricular assist device [VAD] implant),
2. 45-, 90-, and 180-day *time to* first occurrence of all-cause and HF hospitalization, ED visit, or death/cardiac transplantation or VAD implant,
3. 45-day quality of life, functional status and perceived adherence to activity/exercise recommendations,
4. 7-day follow-up appointment with the healthcare provider assigned before discharge.

### Specific aims and hypotheses:

1. Determine the effects of MyROAD on *first occurrence* and *time to first occurrence* of all-cause and HF hospitalization, ED visit, and death (or cardiac transplantation or VAD).

**Hypothesis 1a:** 45-day post-discharge rehospitalization, ED visit and death will be lower or trend toward lower, and 90- and 180-day first occurrence of hospitalization, ED visit and death will be lower in the MyROAD group compared to the usual care group.

**Hypothesis 1b:** Time to first event (rehospitalization, ED visit and death) will be longer in the MyROAD group compared to the usual care group at 90- and 180 days.

2. Determine the effects of receiving repetitive HF messages via MyROAD on quality of life, functional status and perceived adherence to activity recommendations.

**Hypothesis 2a:** Health-related quality of life (specifically, the clinical summary score, quality of life score, total symptom score -and subscales of physical limitations, symptom stability, symptom frequency, and symptom burden- will be higher in the intervention group compared to the usual care group at 45-days, reflecting improved early post-discharge quality of life. [Note: overall summary score (that includes the areas above and also self-efficacy) will be measured but are not included in the endpoint.]

**Hypothesis 2b:** HF-related symptoms will be less prevalent in number in the MyROAD group compared to the usual care group at 45-days.

**Hypothesis 2c:** Functional status will be higher in the intervention group compared with the usual care group at 45-days.

**Hypothesis 2d:** Perceived highest activity/exercise level will be higher in the intervention group compared with the usual care group at 45-days.

3. Determine the effects of receiving repetitive HF messages by MyROAD on adherence to 7-day follow-up appointment after index discharge.

**Hypothesis 3:** Adherence to 7-day follow up appointment will be higher in the intervention group compared with the usual care group.

## **METHODS**

**Design:** The study will use a 2-group, randomized, placebo-controlled, single blinded, design. Healthcare providers will be initially blinded to group assignment, but may learn about the card from patient verbalization over time, as it is not possible to blind patients to the intervention, a MyRoad card.

In brief, the research intervention is a novel card with 4 standardized, recorded messages of HF discharge instructions and a general message. (see Intervention section). The messages themselves are *not* the intervention, as the HF self-care messages are general standard of care messages delivered in many formats to hospitalized patients at all Cleveland Clinic hospitals. It is the ability to re-play (and re-listen) to general messages when desired that is the intervention.

### **Sample and Setting**

A total of 1066 patients will be enrolled (533 per group) and consist of adults with chronic HF (diagnosis  $\geq$  2 months) who are hospitalized for acute decompensated HF at the Cleveland Clinic main campus, Fairview Hospital, and Hillcrest Hospital. This sample size includes a 10% attrition rate.

Patients will have decompensated HF with preserved or reduced ejection fraction when hospitalized and New York Heart Association FC III or ambulatory IV. Diagnosis and etiology of HF will be confirmed in the electronic medical record prior to enrollment.

### *Inclusion Criteria:*

1. Not referred for cardiac transplantation or ventricular assist device during the index hospitalization,
2. Minimum age 18 years (no upper age limit),
3. Ability to read and write,
4. Discharge to home or to a family member's home and has control of making self-care decisions,
5. Willing to participate; which requires three (3) follow-up telephone calls post-discharge.

### *Exclusions:*

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1. Chart documented psychiatric or cognitive conditions that limit ability to understand or adhere to self-care recommendations (Alzheimer's condition, dementia, schizophrenia, other neurological history that impairs memory),
2. Plans to discharge to assisted living apartment/center, skilled nursing facility or hospice care center,
3. Receiving home hospice or palliative care; or has a medical condition reflecting less than 1 year of survival (cachexia, end stage liver disease or cancer or non-ambulatory New York Heart Association functional class IV heart failure),
4. Post-cardiac transplantation or ventricular assist device placement,
5. Currently enrolled in another experimental HF research study,
7. Chronic renal failure and receiving chronic hemodialysis therapy for an estimated glomerular filtration rate  $< 30 \text{ mL/minute/1.73 m}^2$ ,
8. A non-traditional form of HF (hypertrophic or restrictive forms of cardiomyopathy, congenital heart disease or Takotsubo cardiomyopathy).
9. Wheelchair bound, uses a cane or walker, or unable to carry out physical activity, including walking, due to a chronic disability or documented medical condition.

### **Intervention**

MyROAD is a card that has been designed by CC innovators and American Greetings. When the card is opened, there is a general message that is automatically played. Within the card is a heart shaped cutout that has 4 buttons, one in each quadrant. When pressed, each button has audio of one aspect of general HF education: diet, medications, signs and symptoms of worsening condition and physical activity. The buttons can be pressed as desired (for approximately 2 weeks, until the battery expires) to allow playback of messages. At the top of the heart is a space for the phone number of who to call with questions. CCF Marketing and Brand team has been involved in card art and wording including, color choices, formatting, designs and branding/logos. A magnet allows the heart to adhere to metal surfaces as a visual reminder of self-care; see [Appendix A](#). The script was developed by a HF expert clinician (nma) and reviewed and approved by Dr. Randall Starling, vice chair of Cardiology and section head of Heart Failure and Cardiac Transplantation in the Heart and Vascular Institute; see [Appendix B](#). The speaker of the script is a professional radio voice (hired by American Greetings). The card material can be written on, as desired by a health care provider; for example, a nurse can write down the specific dietary sodium limit/day or a phone number. The HF discharge instructions are short, global versions of discharge instructions used by Cleveland Clinic and match current global discharge instruction messages on self-care found in our HF Handbook and HF zones sheet, used by all CC hospitals in Northeast OH.

### **Outcomes and Measurement**

Case report forms will be used to collect all-cause and HF hospitalization, ED visit, and death (or cardiac transplantation or VAD) healthcare consumption and also, 7-day adherence to the scheduled post-discharge follow-up appointment.

- Data will be collected at baseline and 45-, 90-, and 180-day days after discharge

Quality of life will be measured using the *Kansas City Cardiomyopathy Questionnaire* (KCCQ). Kansas City Cardiomyopathy Questionnaire (KCCQ) is a 23 item questionnaire that measures

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physical limitations, symptoms, self-efficacy, social interference and quality of life.<sup>18, 19</sup> KCCQ is valid, reliable and a responsive health measure.<sup>18</sup> When 2 generic QOL tools were compared to KCCQ at baseline and 6 weeks for clinical changes, the KCCQ outperformed the 2 generic tools (EQ-5D and Rand 12).<sup>19</sup> Ultimately, a mean change in score by 4.5 points (higher or lower) at 6 weeks reflected a change by 1 New York Heart Association functional class for overall summary score and a mean change in score by 5 points (higher or lower) at 6 weeks reflected a change by 1 New York Heart Association functional class for clinical summary score.<sup>19</sup> Further, in previous research conducted at Cleveland Clinic in a study of patients with HF and similar enrollment criteria, the KCCQ was highly sensitive to changes in 60-day HF-related QOL between usual care and a 1-liter fluid restriction groups.<sup>20</sup>

- Data will be collected at baseline and 45 days after discharge

Symptoms will be measured using a case report form that contains a list of commonly reported symptoms. Patients would place a check mark in the box of symptoms they have had in the last 7 days. This tool is essentially 1 item and should take about 30-60 seconds to complete. The tool has been used in previous research by the principal investigator and in analysis, patient perceptions of many signs and symptoms were highly associated with functional status and hospitalization.

- Data will be collected at baseline and 45 days after discharge

Functional status will be measured using the Duke Activity Status Index (DASI). The Duke Activity Status Index (DASI)<sup>21</sup> developed in a sample of people undergoing cardiac exercise testing and now routinely used to assess functional status in patients with cardiac disease. The DASI is a 12-item questionnaire using a Likert-like scale that determines a patient's ability to participate in common, everyday activities without difficulty, including self-care activities (1 item), ambulation (4 items), housework (3 items), yard work (1 item), sexual relations (1 item), and recreational activities (2 items).<sup>21</sup> Each item is weighted to reflect the metabolic equivalent (MET) used during the activity. A total score reflects functional status based on responses to each item. Scores can range from 0 (most severe functional impairment) to 58.20 (no functional impairment). Several investigators have investigated the reliability and validity of the DASI.<sup>21-24</sup> The internal consistency of the DASI measured by Cronbach's alpha has been found to be acceptable in HF patients.<sup>22</sup> Test-retest reliability also was examined and determined to be acceptable in patients with HF.<sup>22</sup> The validity of DASI was demonstrated in subjects undergoing graded exercise testing who demonstrated a high correlation (Spearman correlation coefficient from .58 to .80) with peak oxygen uptake.<sup>21</sup> In addition, the DASI varied in a consistent manner according to different clinical factors known to affect patient functional capacity in patients with cardiac disease.<sup>23</sup> When DASI results were correlated with other functional and health status measures, moderate to strong correlations were found: New York Heart Association ( $r$ , -.64;  $P$  < 0.001); six minute walk test ( $r$ , .44;  $P$  < 0.01); Kansas City Cardiomyopathy Questionnaire physical limitations component ( $r$ , .68;  $P$  < 0.001); Kansas City Cardiomyopathy Questionnaire clinical summary ( $r$ , .60;  $P$  < 0.001) and estimated metabolic equivalents calculated from peak treadmill speed and grade ( $r$ , .46;  $P$  < 0.01).<sup>24</sup>

- Data will be collected at baseline and 45 days after discharge



Perceived adherence to activity/exercise recommendations will be measured using an investigator-developed form that is an extension of the physical activity and exercise case report form used in the 2009 exercise study conducted by the PI. The modified PACE tool is a 1-item tool with 17 response options that requires patients to select the option that reflects the highest level of purposeful walking, or moderate or vigorous exercise. The original PACE tool had 11 response options and focused only on moderate to vigorous exercise.

- Data will be collected at baseline and 45 days after discharge

Case report forms will be used to collect patient characteristics and medical history at baseline. The *Charlson Comorbidity Index* will be used to collect medical history. This index was developed to classify comorbid conditions which might change the risk of mortality.<sup>25-30</sup> The score will be categorized into 3 groups (score of 1-2 = 1; 3-4 = 3; 5 or more = 5). In one study with 33,940 patients with ischemic heart disease, the grouping demonstrated a strong relationship with mortality rate.<sup>30</sup> This data will also be used to describe the sample groups for similarity in acuity.

- Data will be collected at baseline.

### **Data Collection**

Medical records will be assessed for inclusion and exclusion criteria before approaching patients. Research personnel will explain the study in a patient's room (private in the J building and with the room-separating curtain closed when a double room on Main campus or at Hillcrest or Fairview Hospitals). After received verbal informed consent, patients will complete baseline data. After completing baseline paperwork, patients will be randomly assigned to the usual care or usual care plus MyROAD card group using block randomization; with blocks of 20 to decrease the influence of external factors that could alter outcomes. The randomization assignment will be made by a QHS statistician.

After randomization to groups:

- Intervention group patients will receive the MyROAD card by research personnel. The card can be administered at the time of enrollment, there is no need to wait till day of discharge, since voice-recorded messages are standard care and are not individualized. Patients will also be instructed that their healthcare providers (including their nurse caregivers) will deliver usual care discharge instructions and patient education.
- Usual care group patients will be instructed that their healthcare providers (including their nurse caregivers) will deliver usual care discharge instructions and patient education.

7-day follow up appointments are part of usual care. A research nurse will review EMRs of enrolled patients between discharge and 30 days after discharge for adherence to the 7-day follow-up appointment. If not found, at the 45-day telephone call, data will be collected on 7-day follow-up appointment adherence, quality of life, functional status and adherence to activity/exercise recommendations (by short questionnaires) during the telephone call.

45-90 and 180-day healthcare consumption will be assessed in 3 primary ways: EMR review, telephone contact and written paperwork mailed to patient's home (if unable to reach patients by telephone: quality of life, functional status and physical activity/exercise forms-- with a self-

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addressed, pre-stamped envelope for return). In addition, death may be assessed by Social Security Death Index software.

### **Sample Size**

Based on historical readmission rates among subjects receiving the current standard of care treatment (~ 20% and dropping slightly every year), a 30-day readmission rate of 18% is expected. We are also basing the sample size on an expected 90-day rehospitalization rate of 25% and a 180-day rehospitalization rate of 35%; both of which are conservative. Sample size calculations were performed to show minimum sample size needed to detect a decrease of 30% at 30-days, 90-days and 180-days with the addition of the card. In many research studies, trends toward improvement are found at 30 days, but the trend is not significant till further out (90 days or 180 days). Thus, we are hypothesizing that a trend will be seen at 30 days, but that there will be significant differences at 90 days and 6-months. A total sample size of 968, 734 and 468 are needed to achieve 80% power in 30-day, 90-day and 180-day rehospitalization rates, respectively. These calculations assumed a balanced randomization and use of one-sided Pearson chi-square tests with a significance level of 0.05. Calculations were performed using SAS software (version 9.2; Cary, NC). To account for attrition in follow-up, sample size was increased by 10-% at 30-days and 20% at 90- and 180-days, creating ideal sample sizes of 1066 (533 per group; to achieve power at 30-days), 882 (441 per group; to achieve power at 90-days) and 562 (281 per group; to achieve power at 180-days).

- Thus, our *minimum sample size* will be 562 subjects. If trends in outcomes are favorable, data collection will continue to reach the required sample size for 90-day outcomes.

### **Analyses**

Patient characteristics will be summarized using frequencies and percentages for categorical factors, and means, standard deviations, and percentiles of interest for continuous measures. Pearson chi-square tests will be used to compare the proportion of subjects meeting the composite endpoint of death or at least 1 readmission by 6 months. Secondary analyses will use Poisson regression to compare readmission rates (number of readmissions/follow-up days), and competing risk survival methods will be used to compare time to first readmission between groups. Analyses will be performed assuming a 0.05 significance level. Analyses will be performed using SAS software (version 9.2 or higher; Cary, NC).

### **Feasibility**

The main campus of Cleveland Clinic has a high volume of HF discharges each year. Fairview and Hillcrest Hospitals have moderate volumes of HF discharges, and are less likely to have patients who meet exclusion criteria due to enrollment in another research study or advanced HF. Electronic medical records allow for review of data on events that occur in *all* system hospitals and regional medical practice ambulatory care sites; decreasing the need to rely on patient recall of rehospitalization and emergency care events.

The MyCard instructions are a global representation of standard HF discharge instructions found in written handouts and other sources of patient education (videos, verbal instructions from healthcare providers). No new information is presented; thus, the MyRoad card is an extension of usual care delivered in a *different format that is repeatable*. Patients do not need to be able to

read and if they are forgetful, they can replay messages multiple times before the battery cycle ends (around 2 weeks of frequent use).

Nurse managers, clinical nursing directors and cardiologist medical directors of each hospital involved (7<sup>th</sup> floor J building and general medical units of main campus; multiple medical units of Hillcrest and Fairview Hospital—however, patients with HF are concentrated on PK2-Progressive Care Unit [Fairview Hospital] and 5M [Hillcrest Hospital] are aware that this study will be starting and agreed (and were actually excited) that we are included their patients/units. Research personnel from the Office of Nursing Research and Innovation will be involved in recruitment and all data collection. The main campus has multiple research projects in place. My team is accustomed to working with cardiology research nurses to ensure patients are not approached for more than 1 research study.

Self- or research nurse-administered instruments that will be completed at baseline, 45, 90 and 180-days are short, simple and will be quick to complete. Patients may become fatigued when completing data collection forms; however, there are only 5 forms for patients to complete at baseline (quality of life, symptoms, functional status, physical activity/exercise and a case report form of demographic information); all of which are short (most are single page) and should not take more than 10 minutes to complete. The 4 forms used at 45 days should take no more than 5 minutes to complete. We have used all instruments in previous research and do not anticipate a burden to patients who enroll. There is only a telephone call at 90- and 180-days. Data obtained from electronic medical records is consistently present, minimizing the occurrence of missing data.

### **Limitations and Anticipated Problems**

Patients and caregivers may never listen to the recorded message after discharge, or lose, throw out or misplace the card. Patients may hear, but ignore, message content. Patients may drop out before the 180-day follow-up data collection. Patients in both groups may ignore self-monitoring and self-care messages based on past practices, implicit beliefs about how to monitor and care for self or misperceptions of family or friends. Analyses will be completed using “intent to treat” methods. In this way, we will be able to learn the effect size of the intervention among all patients randomized to the intervention group.

No adverse effects are anticipated, as the intervention in this research is a greeting-type card that cannot create harm to patients. The audio script provides global messages of content used in usual care education and discharge instruction materials. There are no risks of adverse events from the intervention itself.

### **Human Subjects Protection**

Approval by the Cleveland Clinic Institutional Review Board will be sought prior to study initiation. We believe this study is minimal risk as the intervention is a greeting-type card that repeats self-care monitoring and instruction messages that are part of usual heart failure post-discharge care.

1 data collection form will use a research number and CCF medical record number; as it will also contain a phone number and address; however, all other forms only contain the research number. Only the research number will be recorded in the electronic database. Paper forms will be kept in a locked cabinet, in a locked office of the principal investigator and will be destroyed upon completion and publication of the study. Electronic data for analysis will use a research number; no patient identifiers will be used. All study results will be reported in the aggregate.

SPSS will be the electronic database used to capture paper data. The database will be maintained for 6 years after study completion. Paper forms will be destroyed after analyses are complete.

This research project may be registered in [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

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Timeline												
Work	2016											2017
	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan
Startup work*												
Patient enrollment, data collection and data entry into database												
Patient 6 month follow-up												

\*, secure cards (after developing wording and card designs); identify and train nurses assigned to project; prepare randomization cards/envelopes; ensure hospital-based nurses are trained in human subject protection; receive IRB for approval to conduct the study, receive support for cardiology directors at each hospital and develop database

Timeline, continued												
Work	2017											2018
	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan
Patient enrollment and data collection												
Patient 6 month follow-up												
Data entry and cleaning												

Timeline, continued							
Work	2018						
	Feb	Mar	Apr	May	Jun	Jul	Aug
Data entry and cleaning							
Data analysis							
Abstract and presentation preparation/delivery (local stakeholders)							

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Abstract submission for national meeting presentation in 2018**							
Prepare paper for publication							

\*\*, American Association of Heart Failure Nurses; American Heart Association

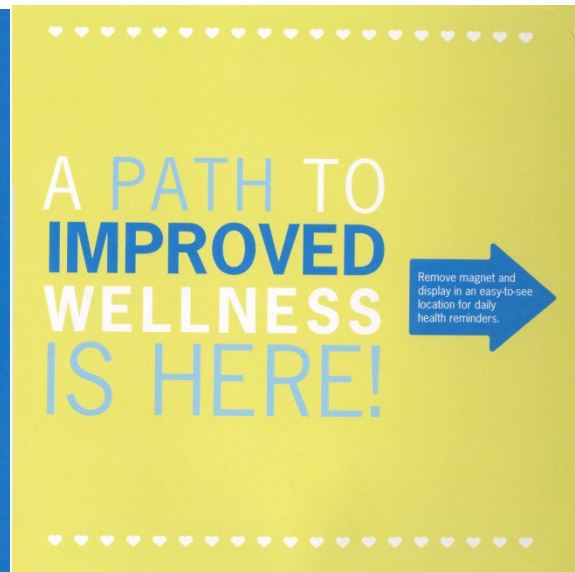


## Appendix A; Prototype of Card

Front of Card (Page 1)



Inside of page 1 (left side)



Page 2 (inside of card-right side)



Back of Card (Page 2)



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## **Appendix B. Audio Script**

### **CLEVELAND CLINIC – MY ROAD CARD**

Script for American Greetings – Heart Failure

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#### **INTRO (plays audio when the card is opened)**

Cleveland Clinic cares about you and your health, so we've designed this message to help you take the best care of yourself after leaving the hospital. The messages in this card will cover important information regarding physical activity, diet, medication, and self-monitoring. Your primary medical diagnosis is heart failure. Heart failure is a chronic condition. It is important to take actions to improve your health and stabilize heart failure. Contact your doctor if you still have questions after hearing and carrying out the actions provided in this card.

#### **PHYSICAL ACTIVITY (Plays when the physical activity button is pressed)**

Physical activity is extremely important for you. Start slow with walking 10 minutes a day. Over the course of a month, build up to walking 30 minutes a day. Do not worry if you feel short of breath or have a fast heart rate as you engage in physical activity – this is all normal. Unless your doctor or nurse specifically advised against walking or completing other physical activities you should be active 5 days per week. If you feel ready for more activity beyond walking, you can try swimming, bicycling, or walking briskly.

#### **DIET (Plays when the diet button is pressed)**

Eat fresh foods as much as possible. Do not take in more than 2900 mg of sodium per day. Avoid eating frozen, boxed, bagged, or canned foods. The 6 most salty foods are breads, soups, breaded meats, pizza, deli meats and deli sandwiches. Please avoid these salty foods. Limit the use of butter and ask your server about sodium content if you eat at a restaurant. Read food labels for sodium content and serving size to learn if you are taking in too much sodium.

#### **MEDICATIONS (Plays when the medications button is pressed)**

Medications are a very important part of heart failure care. They keep your heart from getting bigger and some medications help reduce your heart size and improve your heart's ability to function more normally. Even if you start feeling better, do NOT stop taking your medications. Also, be sure to attend your scheduled office visits so that your medications can be adjusted to the right dose. It is common that a dosing change is needed for 1 or more medications after hospital discharge. Continue taking all of your heart failure medicines as ordered and call your doctor or nurse if you're unsure about anything regarding your medications.

#### **SELF-MONITORING (Plays when the self-monitoring button is pressed)**

Weigh yourself every day. If you gain more than 4 pounds unexpectedly, call your doctor or nurse.

Call your doctor or nurse if any you are experiencing any of these other symptoms:

- New or worsening shortness of breath
- New or worsening fatigue or leg weakness
- New or worsening swelling in the ankles and lower legs
- A firm abdomen around your belly button that does not poke inward easily
- An increase or a new need to urinate at night after going to bed
- Needing more pillows at night or needing to sleep in a recliner, and

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- Finding yourself sitting up in bed at night to catch your breath.

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