Published in final edited form as:

J Am Med Dir Assoc. 2013 September ; 14(9): 710.e5–11. doi:10.1016/j.jamda.2013.05.023.

A Randomized Trial of Heart Failure Disease Management in Skilled Nursing Facilities: Design and Rationale

Rebecca S. Boxer, MD, MS^{*}, Mary A. Dolansky, RN, PhD[†], Christine A. Bodnar, BSN, RN^{*}, Mendel E. Singer, PhD, MPH[‡], Jeffery M. Albert, PhD^{‡,§}, and Stefan Gravenstein, MD, MPH[§]

^{*}Harrington Heart and Vascular Institute, Case Western Reserve University, Cleveland Ohio

[†]Francis Payne Bolton School of Nursing, Case Western Reserve University, Cleveland Ohio

[‡]Department of Epidemiology and Biostatistics, Case Western Reserve University, Cleveland Ohio

[§]Center for Geriatrics, Case Western Reserve University, Cleveland Ohio

Abstract

Background—Heart failure disease management can improve health outcomes for older community dwelling patients with heart failure. Heart failure disease management has not been studied in skilled nursing facilities, a major site of transitional care for older adults.

Methods and Anticipated Results—The objective of this trial is to investigate if a heart failure disease management program (HF-DMP) in skilled nursing facilities (SNF) will decrease all-cause rehospitalizations for the first 60 days post SNF admission. The trial is a randomized cluster trial to be conducted in 12 for-profit SNF in the greater Cleveland area. The study population is inclusive of patients with heart failure regardless of ejection fraction but excludes those patients on dialysis and with a life expectancy of 6 months or less. The HF-DMP includes 7 elements considered standard of care for patients with heart failure: documentation of left ventricular function, tracking of weight and symptoms, medication titration, discharge instructions, 7 day follow up appointment post SNF discharge, patient education. The HF-DMP is conducted by a research nurse tasked with adhering to each element of the program and regularly audited to maintain fidelity of the program. Additional outcomes include health status, self-care management, and discharge destination.

Conclusion—The SNF-Connect Trial is the first trial of its kind to assess if a HF-DMP will improve outcomes for patients in SNFs. This trial will provide evidence on the effectiveness of HF-DMP to improve outcomes for older frail heart failure patients undergoing post-acute rehabilitation.

© 2013 American Medical Directors Association. Published by Elsevier Inc. All rights reserved.

Corresponding Author: Rebecca S. Boxer, MD, MS, Harrington Heart and Vascular Institute, University Hospitals, Case Medical Center, 11100 Euclid Ave, Cleveland, OH 44106, rebecca.boxer@case.edu, Phone: 216-844-7726, Fax: 216-844-8954. Alternate Corresponding Author: Mary Dolansky, Francis Payne Bolton School of Nursing, Case Western Reserve University, Cleveland, OH 44106, Mary.Dolansky@case.edu, Phone: 216-368-0568.

Publisher's Disclaimer: This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

Clinical Trials Registration: www.clinicaltrials.gov: NCT01822912

Conflict of Interest

All authors - none

Keywords

Heart Failure; Disease Management; SNF

Introduction

Heart failure challenges our clinical management skills through unpredictable exacerbations, frequent hospital utilization, and complicated treatment regimens. Older adults prove particularly challenging due to additional morbidities, altered medication tolerance, cognitive and physical decline, and often lack of social support. In the setting of system-wide financial penalties for rehospitalizations from Medicare, evidence-based strategies to reduce rehospitalizations in older adults are needed. Community HF-DMPs have evidenced success through reduced hospitalizations, mortality and improved quality of life.^{1,2} The effectiveness of HF-DMP in reducing re-admissions from the post-acute rehabilitation setting remains unknown. The rehabilitation and transitional setting receives some of the sickest and most medically complicated heart failure patients.

The purpose of the SNF Connect Study is to determine whether a HF-DMP can reduce rehospitalizations for older adults. The study focuses on the immediate post-acute patient (i.e. 30 days post hospital discharge) and the immediate post-SNF (skilled nursing facility) discharge (i.e. 60 days post SNF admission). The study period has been chosen to illuminate the effects of the HF-DMP during the vulnerable time period when the patient transitions from one care site to the next.

The SNF provides an ideal setting to initiate a HF-DMP as it already relies on a multidisciplinary team for patient care. McAlister et al have already demonstrated the effectiveness of the team approach for HF disease management.³ We hypothesized that a SNF HF-DMP will reduce rehospitalization rates compared to usual care (UC) for the first 30 days post hospital discharge and 60 days after SNF admission.

The Study Partnerships

Partnerships were formed with multiple community-based for-profit SNFs. We chose for-profit entities as they hold 70% of the market share⁴ and increase the chances for rapid dissemination of practice change through the corporate structure. The pressure to reduce readmissions and the marked competition between the facilities to demonstrate the ability to manage these complex patients has primed the healthcare climate for our study. In the greater Cleveland area, it has resulted in enthusiastic cooperation from the facilities and their affiliated companies.

Trial Population

We plan to enroll 1404 patients admitted to a SNF following an acute-care hospital discharge with a principal or secondary diagnosis of HF and independent of ejection fraction. Inclusion and exclusion criteria are listed in Table 1. We include cognitively impaired patients to improve the generalizability of our study population. These patients required a caregiver who is the identified key learner to assist in HF management at home.

Sample characteristics focus on relevant geriatric phenomena common in the SNF setting and associated with adverse outcomes but rarely collected for HF trials. These include a frailty measures (15 foot walk plus hand grip strength), comorbidity, cognitive impairment and delirium. When possible, instruments already used in the SNF are used to assess patients. For example to detect dementia and delirium, the Minimum Data Set measures

[Brief Interview for Mental Status (BIMS) and Confusion Assessment Method (CAM)] will be used. These measures are collected by the research staff at the time of enrollment since the SNF staff may not complete the MDS until 14 days after admission. Detailed description of the HF patient population in SNF provides future opportunity to further tailor interventions.

Trial Design

Considerations to Reduce Bias

The study employs a blocked, cluster randomization design,⁵ with physicians, defined as either high or low admitters, serve as clusters, and SNFs as blocks. This provides the best opportunity for balance between groups. Using the SNF as the block takes advantage of any within-SNF correlation (besides that due to a physician) to increase power. Specifically, for each SNF we randomize the patients by physicians/physician group to either a HF-DMP or UC in a 1:1 ratio. This avoids contamination between the intervention and the UC group through the physician practice. A constrained randomization is used to balance the number of physicians assigned to each study arm within each SNF.

Intervention: Heart Failure Disease Management Program

The intervention was designed to fit with measures collected in the acute care setting to ease the transfer of information. The intervention's simplicity makes it readily replicated and sustained; if proven effective. The intervention is conducted by a HF Nurse Advocate, (HFNA) who implements the intervention; the facility staff do not conduct the intervention.

The HF-DMP applies the important elements of care transitions and specific HF components recommended by the National Priorities Partnership, Hospital to Home initiative and the American Heart Association Get with the Guidelines Program for the transition from hospital to home. Therefore, the SNF HF-DMP builds on the approaches modeled by national organizations across the continuum of care. The American Heart Association/American College of Cardiology HF Guidelines and Clinical Performance Measures were also used to develop our intervention.⁶⁻⁸ The HF-DMP emphasizes two components of SNF HF care, clinical management and patient/caregiver self-efficacy at discharge. Clinical management of HF intends to optimize medical therapy. The fostering of self-efficacy centers on iterative education both conceptually and through coaching of HF self-care techniques for the duration of the SNF stay, at discharge, and at 7 day follow-up. HF disease management programs led by nurses can improve both patient quality of life and cost effectiveness.⁹ Figure 1 illustrates the 7 measures of the two components of the HF-DMP: the Clinical Care Measures and the Discharge Care Measures.

The HFNA assures that each care measure is performed on each patient. Enrolled patients are followed through to 60 days post SNF admission. This duration permits us to capture patient activity and learning both during the SNF stay and immediately post-SNF discharge since the average length of SNF stay is 21 days. Since the length of stay varies for each patient, the seven measures of the HF-DMP are scheduled according to the SNF staff's best prediction of length of stay. The HFNA meets with SNF staff at admission and throughout the patient's stay to assure that the HF-DMP moves forward at an appropriate rate for the patient's anticipated discharge.

HF-DMP Clinical Care Measures—The clinical care measures provide the necessary patient data to support the up-titration of disease and symptom modifying medications according to the HF Guidelines.⁸

1. Document the left ventricle ejection fraction (LVEF): The LVEF guides therapy for patients with HF. Documentation of LVEF is an established performance measure for patients in the inpatient and outpatient settings.⁶ Our preliminary data showed that none of the SNFs we studied systematically acquired LVEF.¹⁰ This handicapped the SNF physicians' ability to appropriately medicate their patients. The HFNA acquires LVEF on all patients admitted to SNF. The HFNA will assure that LVEF is documented in the patient's chart. For EFs $\leq 40\%$, the practice guidelines for systolic failure will be used.⁸ For HF-PEF (EFs $>40\%$), where the guidelines are less clear, the goal is to adhere to the JNC 7 guidelines for hypertension: reducing blood pressure $\leq 130/80$.¹¹

2. Symptom and Activity Assessment: Recognition of clinical deterioration has been demonstrated to be an important first step to effective HF-DMPs.¹² The HFNA assesses the patient and documents HF signs and symptoms (dyspnea, orthopnea, paroxysmal nocturnal dyspnea, jugular venous distention, edema, abdominal bloating) and assigns the New York Heart Association (NYHA) functional class three times weekly. The NYHA classification allows standardization of identification of symptoms as they relate to activity. Symptoms and activity can assist in treatment decisions. Symptom and activity assessment has been added by the Physicians Consortium for Performance Improvement as an important measure for patients with HF.¹³

3. Daily Weights/Dietary Surveillance: Tracking the patient's weight, signs and symptoms helps in the assessment of their volume status over time and determine their response to medical therapy. The HFNA gets a post-micturition weight on each patient 3 times a week in similar clothing. To prepare for the transition to home, weights are recorded on a calendar with the patient and/or their caregiver observing how to track weight over time. The caregiver can serve as an important check, but also serves as the stand-in to appropriately monitor and intervene for cognitively impaired patients. Each patient and/or caregiver will be instructed on dietary surveillance for sodium. The lowest sodium diet available in the SNF will be requested on all patients. Patients will also be instructed which foods to avoid based on the SNF menu and alternatives to choose. Patients and caregivers will be instructed on a similar strategy (including reading food labels) at home.

4. Medication Titration: Optimization of medication is an important component of successful HF-DMPs.¹² Older adults including those in nursing facilities are under-medicated for HF.^{14,15} Older adults are perceived to be less tolerant of medications than middle aged adults, but evidence indicates prescribing medications adhering to HF guidelines reduces morbidity and mortality, even in the long-term care setting.^{16,17} Older adults can tolerate and benefit from up-titration of their HF medication, but they need closer monitoring for adverse drug reactions. ACE-inhibitor and beta blocker protocols are offered to those with systolic failure and blood pressure control, i.e., to those HF patients with an EF $>40\%$. A flexible diuretic regimen will be available for all patients. For additional support the physicians randomized to the HF-DMP will receive instruction on HF physiology and the value of medication up-titration. After evaluating the patient, the physician approves the up-titration protocols or documents the reason for patient exemption (e.g. patient has not tolerated the medication in the past).

HF-DMP Discharge Care Measures

1. Patient and Caregiver Education: Patients and caregivers in the HF-DMP group receive education. Teaching points for the patients about self-management of HF is provided in 5 lessons during their stay in a preset sequence. Teaching points are brief and are consistent with the HF care they receive. Small frequent teaching sessions take advantage of the longer stay for patients in SNF rehabilitation programs, an approach less manageable during

relatively short hospitalization stays where a discharge educator typically provides the instructions at the time of discharge. Teach-back will be used to assess the understanding of the content.^{18,19} Teaching points are summarized in 5 separate instructional pages for the patient and caregiver: *Managing Your Heart Failure* and the other *Caregiving in HF*.

2. Discharge Instructions: All HF patients in the HF-DMP group get written discharge instructions which include the same elements demonstrated and taught during their SNF stay: recognizing signs and symptoms of HF, monitoring weight daily and tracking it on a calendar recognizing and understanding HF medications, following a low sodium diet and knowing when to call the doctor.

3. Follow Up Appointment in 7 days post SNF discharge: Patients discharged home from the hospital with an early post-hospital follow up appointment have the lowest rehospitalization rate.²⁰ We expect that an early post follow-up appointment from SNF can position patients to reduce their rehospitalization risk after SNF discharge. The transition from SNF to home is a vulnerable time for the patient/caregiver as they take over the care SNF staff provided. Each patient in the HF-DMP group receives an appointment with the HFNA about a week post SNF discharge. Seven days was chosen to remain consistent with other national initiatives.⁷ The HFNA will conduct the follow-up appointment at the SNF. This is ideal since the HFNA is familiar with the patient and is able to initiate further evaluation if needed. Familiarity with the patient at follow-up is an important component to the patients successful avoidance of rehospitalization.²⁰ Furthermore, the HFNA will not need to rely on the outpatient physician's availability for the 7 day follow up which can often be difficult to schedule. At the follow-up appointment the HFNA will review and reconcile medications and medication adherence, evaluate for signs and symptoms of HF, review the patient's daily weight calendar and inform the outpatient physician of the patient's status.

Usual Care (UC)

Physicians patients randomized to the UC group continue to provide their patients their UC practices. The research assistant abstracts the patient charts for the same seven HF-DMP measures if performed during the course of UC. This will include any medication changes, and reasons for the changes.

Fidelity of the Intervention

It is important that all the elements of the HF-DMP are performed consistently to test if a HF-DMP improves outcomes in SNF. The HFNA will be trained in best practices for HF prior to the onset of the study to assess patients with HF and effectively collect and deliver each of the 7 measures of the HF-DMP. The HFNA will undergo standardized didactic training using National Heart Failure Training Program Bridge Project online curriculum¹⁰ as well as case examples to highlight obstacles encountered within the SNF environment. HFNA will be videoed delivering the HF-DMP to a standardized patient to assess the HFNA skills prior to initiation of the HF-DMP.

Quality control will entail monitoring for drift of HFNA skills. A research assistant, independent of the HFNA, will monitor the HF-DMP measures by performing weekly audits on a random selection of patient participants to measure fidelity of the intervention. The HFNA will be provided a weekly report of audits and if the elements of the HF-DMP are not successfully met, retraining will occur. Weekly team meetings will take place to resolve problems that may threaten the implementation or the fidelity of the HF-DMP implementation.

Primary and Secondary Endpoints

A major goal of this trial is to determine if disease focused management will change outcomes for patients with HF. The primary and secondary endpoints are listed in Table 2. There are two time points to capture for rehospitalizations, at 30 days and 60 days post-SNF admission. These two time points help inform if the HF-DMP intervention changes outcomes at the Medicare issued 30 day reimbursement time point as well as the immediate post-SNF discharge time period, captured at the 60 day mark. All hospital admissions are collected for 60 days post-SNF admission to quantify those who are readmitted multiple times during the study period.

Health Status will be measured by the Kansas City Cardiomyopathy Questionnaire (KCCQ) which is a 23 item questionnaire specific for patients with HF. It includes aspects of physical function, symptoms (frequency, severity and stability), social function, self-efficacy, knowledge, and quality of life. The KCCQ was chosen in that it has been deemed more sensitive than other health status assessment tools.^{19,20} The KCCQ will be measured on each patient at SNF admission and at 60 days post SNF admission.

HF Self-Management is measured using the Self Care HF Index (SCHFI) which consists of 15 item scale with 3 domains of self-care including self-care maintenance (behaviors to maintain clinical stability), self-care management (decision making process with regard to symptom changes), and confidence to manage symptoms. The SCHFI will be measured on each patient at SNF admission and at 60 days post SNF admission by the research assistant at the patient's home or other location.

Discharge Destination is where patient goes upon discharge from SNF. Discharge destination includes home, assisted living facility, long term care, hospice or death. Residential location at 60 days post SNF admission is compared to residential location prior to index hospital admission. Discharge to a SNF post-acute care for chronically ill medical patients may be a marker for decline in independence and function. Comparing pre-hospital admission residence to post-SNF discharge in a broad sense will capture this change in independence. Our pilot data indicated that many of the HF patients who were living at home prior to their hospitalization and who were admitted to SNF did not return home. Understanding the trajectory of care for HF patients who transitions through SNF is important to the design of future interventions and allocation of resources to improve HF care.

Covariates

Demographic information is collected in both study groups and includes: age, sex, race, ethnicity and details of the medical history. Variables known to be important to outcomes in HF: serum sodium, hemoglobin and the glomerular filtration rate are collected from the last hospital serum analysis prior to SNF admission or, if collected, at the time of SNF admission. Change in medications and doses are collected throughout the SNF stay. Other important characteristics which are common in this patient population and have the potential to affect outcomes are also collected to capture a holistic view of these older adults and to understand what drives adverse outcomes.

Frailty is defined as a poor ability to cope with physiological stress and has demonstrated a strong association with a diagnosis of HF in observational studies.²³⁻²⁷ There is no direct clinical test to measure frailty, and the challenge is to identify proxy measures which can serve as an indicator of this vulnerable state. Many measures, employ a multidimensional approach to capture the essence of this phenomenon.^{26,23} Comparison of multiple frailty measures in the long term care population have all shown utility in predicting outcomes.²⁹

Gait speed has been identified as one of the best single item screening tools for frailty and is predictive of poor outcomes in community dwelling older adults.³⁰ We have found that for older adults with HF that a walk test is associated with a multidimensional measure of frailty.³¹ The participants in this proposed study will be characterized by walk speed on the 15 foot walk which is the distance used in the Frailty Phenotype.²⁵ The 15 foot walk will be tested within the first 4 days of admission to the SNF. Four days will be permitted so that the physical therapy evaluation can first be completed to assure safety with the walk test. A second measure associated with frailty and used as one of the components of the Frailty Phenotype is handgrip strength. Handgrip strength is associated with outcomes in newly diagnosed patients with HF³² and useful to assess the non-ambulatory patient. Handgrip is also collected at baseline and at the time of discharge.

Comorbidity is measured using the Charlson Comorbidity Index (CCI) and collected at SNF admission. The instrument measures the number and seriousness of co-morbid diseases using a weighted index.³³ The CCI has been shown to be associated with a variety of outcomes such as mortality, disability, readmissions and length of stay.³² The CCI has been used with older cardiac patients in previous studies.³³

Cognitive Impairment is measured by the Brief Interview for Mental Status (BIMS). Adequate cognitive function is vital to self-care management and will trigger caregiver teaching of self-care techniques in HF. The BIMS is routinely collected as part of the Minimum Data Set (MDS) at admission to SNF and includes measures of repetition, orientation and recall. The BIMS was chosen over other measures of cognition since it is used in routine practice in SNF.

Delirium is measured using The Confusional Assessment Method (CAM) at admission to SNF. Delirium is a common phenomenon for older adults discharged from acute care and is associated with morbidity and mortality.³⁶⁻³⁹ It is important to evaluate delirium in addition to cognitive impairment since delirium can have a major effect on outcomes for older adults discharged from the hospital to SNF.³⁸ The CAM is measured routinely as part of the MDS 3.0. Since delirium waxes and wanes and may completely clear over the SNF stay, patients will not be excluded based on their initial CAM score. The CAM will be repeated up to 3 times the week after admission by the HFNA in order for the patient not to be excluded from the baseline measures for health status and self-care. If a delirium free period has not been identified for the evaluation then the subject will be consented into the cognitively impaired group and excluded from health status and self-care assessment.

Statistical Analysis

Effect of Intervention on the Composite Endpoint

The planned analysis fits a mixed effects logistic regression model for the binary individual-level outcome of occurrence or non-occurrence of an unplanned event (including all cause hospitalization, ED visit, or death) in 30 days following hospital discharge. This model includes a random effect for physician, an indicator variable for intervention, and an a priori selected set of covariates (representing prognostic baseline variables, see above). If substantial differences in event rates among SNFs are found, we will consider inclusion of either a random or fixed effect for SNF. We will select among competing models using the Akaike Information Criterion (AIC).⁴⁰ The exponentiated coefficient of treatment in this model is interpreted as the (common) physician-specific odds ratio (for HF-DMP versus UC). We also use a model-standardization approach⁴¹ to obtain an estimate of the relative risk, that is, the proportional increase or decrease in the (population) probability of an event for HF-DMP versus UC. A bootstrap approach will be employed to obtain a 95% confidence interval for the relative risk.

A similar approach is used to compare HF-DMP and UC groups in the proportion of patients who are at home 60 days following SNF admission. This analysis involves the subset of patients who were previously living at home.

Effect on Health Status and Self-management

An additional goal is to compare health status (KCCQ) and HF self-management ability (SCHFI) between the HF-DMP and UC groups. The planned analysis fits linear mixed effects models separately to the two outcomes (KCCQ and SCHFI, assumed to be roughly normally distributed). This analysis includes cognitively intact HF patients (defined at baseline). As in the above nonlinear models, the linear models include an indicator variable for treatment group, a predetermined set of baseline covariates and random effect for physician. We are also considering a two-level model using the SNF as the first cluster level and physician within SNF as the second cluster level. This analysis is complicated by the fact that some physicians work at multiple SNFs. If possible, this overlap will be considered, otherwise a simplifying assumption of independence across SNF will be made.

Model fit is assessed using AIC and the normality assumption checked using the Shapiro-Wilk statistic. T-tests for the mixed effects model will be used to test for a non-null treatment effect for each outcome. In addition, the mean difference for each outcome variable between intervention groups will be estimated and a 95% confidence interval for these differences obtained.

Cost-Effectiveness

Assessment of the cost of the intervention and the corresponding potential cost avoidance, figure importantly into our study. HFNA time drives the majority of the cost of the HF-DMP intervention and includes training and time spent on the intervention. The cost of the HFNA is based on hours of time spent on interventions multiplied by the prevailing wages for an equivalent person working in the SNF setting. Our wage estimates came from the Occupational Employment Statistics website at the Bureau of Labor Statistics (<http://www.bls.gov/oes/home.htm>). The cost of rehospitalizations and emergency department visits are compared between the intervention and UC groups. These costs are estimated from discharge and/or billing records, information from Medicare reimbursement data for similar emergency department visits and from the National Inpatient Sample (NIS). Using a combination of diagnosis codes, procedure codes and inpatient Diagnosis Related Group (DRG) codes, we can determine a nationally representative cost for emergency and inpatient services similar to the ones experienced in the study. This is possible due in part to the NIS including both charges and a hospital-specific cost-to-charge ratio to convert a hospital's charges to cost. Weighing the direct cost of intervention against cost savings from reduced emergency and inpatient care provides a balanced view of the true net cost of the intervention. This is an important perspective for policy makers. However, for SNFs, the cost of the direct intervention alone is of primary importance.

Discussion

The SNF Connect Trial is the only study of HF-DMP exclusively in the skilled setting. Studying patients in SNF gains access to a relatively uniformly frail HF population immediately post hospitalization. It is unknown if the standard of care for HF will have any benefit in this patient population. SNFs have already been identified as a place associated with poor outcomes for patients with HF.⁴² A disease focused management plan for the SNF population may be too narrow in focus to change outcomes since many of these patients are medically complicated. However, the standardization of care (particularly pharmacologic therapy) for patients with HF has proven to greatly improve outcomes for

younger patients who are typically the participants in clinical trials for HF⁴³ and is worth rigorous testing in this population of patients.

HF-DMPs generally could favorably influence outcomes.^{3,44} However, programs include different components delivered in different settings and with variable uses of technology, which makes comparisons between programs difficult. No one element of these programs has proven more effective than another, but often a knowledgeable and capable nurse is central. Therefore, we designed a nurse driven program, which is also the most reasonable approach, from a cost perspective, for SNFs.

Testing a HF-DMP in SNF presents several challenges. It requires participation of multiple corporate entities to accept research of unknown outcomes in their facilities. Pilot work demonstrated that instituting a research protocol and HF-DMP in SNF would not be possible with SNF staff due to low staff numbers, lack of knowledge in HF disease management, and frequent disruptions due to surveys.¹⁰ The SNF vary in the care provided and the procedures followed. The presence of clinically knowledgeable staff is highly variable and frequent staff turnover is problematic especially when it displaces newly introduced knowledge and wasted resources. To overcome the challenging SNF environment we use our own trained research team to deliver the HF-DMP. We suspect that the SNF obstacles to implementation of a HF-DMP are not unique to our region. However, if the HF-DMP improves outcomes and reduces cost, corporate SNFs are best poised to systematically adopt the HF-DMP protocols, train their own HFNA and institute changes across multiple facilities.

Physician support and buy-in presents an additional challenge. Physicians working in the SNF are typically in private practice and research is not often in their scope of practice. Since the HF-DMP requires some physician involvement (i.e. to endorse titration of medications according to protocols), we incentivized physicians to engage in our program. For the most part, physicians recognize that the HF-DMP can assist in monitoring their patients and are willing to participate.

The HF-DMP is a low risk intervention. However, medication titration poses a unique challenge in the SNF patient population. Older adults, including the oldest old, are at increased risk for adverse events related to HF medications. The high number of comorbidities and polypharmacy requires increased attentiveness to drug-drug and drug-disease interactions. Physicians working in the SNF setting may not be comfortable with guideline recommended medications and doses. Therefore, medications and dosing protocols are offered when appropriate but not required. Data collection includes reasons for protocol refusal so that the concerns of the physicians and obstacles for medication management are captured.

Conclusions

The findings from this trial are important to the care of older adults with HF who are discharged from the hospital to SNF. The unique characteristics of this population of HF patients collected during the trial provide an important dataset for future study. Those patients who go to SNF anticipate achieving a level of independence at least to that prior to hospitalization. The cluster trial design overcomes many of the biases which are inherent to this type of study. The HF-DMP is treated as a “dose” with careful auditing to maintain control over the protocol to assure it is delivered effectively. At the trial completion we will have a better understanding of the population of patients with HF who go to SNF and if a HF-DMP improves outcomes.

Acknowledgments

This project is made possible through grant NIH 5R01HL113387-02.

References

1. Stewart S, Horowitz JD. Home-based intervention in congestive heart failure: long-term implications on readmission and survival. *Circulation*. 2002; 105:2861–6. [PubMed: 12070114]
2. Rich MW, Beckham V, Wittenberg C, Leven CL, Freedland KE, Carney RM. A multidisciplinary intervention to prevent the readmission of elderly patients with congestive heart failure. *N Engl J Med*. 1995; 333:1190–5. [PubMed: 7565975]
3. McAlister FA, Stewart S, Ferrua S, McMurray JJ. Multidisciplinary strategies for the management of heart failure patients at high risk for admission: a systematic review of randomized trials. *Journal of the American College of Cardiology*. 2004; 44:810–9. [PubMed: 15312864]
4. MedPac. Medicare Payment Advisory Commission Report to Congress. 2011. Section 7
5. A D. N K. Design and analysis of cluster randomization trials in health research. Hodder: Arnold Publication; 2000.
6. H2H Hospital to Home. [accessed 12/10/2012] Reducing Readmissions Improving Transitions. Available at <http://H2Hquality.org>
7. <http://H2Hquality.org>. In.
8. Hunt SA, Abraham WT, Chin MH, et al. ACC/AHA 2005 Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Update the 2001 Guidelines for the Evaluation and Management of Heart Failure): developed in collaboration with the American College of Chest Physicians and the International Society for Heart and Lung Transplantation: endorsed by the Heart Rhythm Society. *Circulation*. 2005; 112:e154–235. [PubMed: 16160202]
9. Hebert PL, Sisk JE, Wang JJ, et al. Cost-effectiveness of nurse-led disease management for heart failure in an ethnically diverse urban community. *Ann Intern Med*. 2008; 149:540–8. [PubMed: 18936502]
10. Boxer RS, Dolansky MA, Frantz MA, Prosser R, Hitch JA, Pina IL. The Bridge Project: improving heart failure care in skilled nursing facilities. *Journal of the American Medical Directors Association*. 2012; 13:83 e1–7. [PubMed: 21450244]
11. Chobanian AV, Bakris GL, Black HR, et al. Seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. *Hypertension*. 2003; 42:1206–52. [PubMed: 14656957]
12. Yu DS, Thompson DR, Lee DT. Disease management programmes for older people with heart failure: crucial characteristics which improve post-discharge outcomes. *Eur Heart J*. 2006; 27:596–612. [PubMed: 16299021]
13. [accessed 12/3/12] Heart Failure Performance Measure Set. Physician Consortium for Performance Improvement 2011. Available at: <http://www.ama-assn.org/ama1/pub/upload/mm/pcpi/hfset-12-5pdf>
14. Gambassi G, Forman DE, Lapane KL, et al. Management of heart failure among very old persons living in long-term care: has the voice of trials spread? The SAGE Study Group. *Am Heart J*. 2000; 139:85–93. [PubMed: 10618567]
15. Saczynski JS, Darling CE, Spencer FA, Lessard D, Gore JM, Goldberg RJ. Clinical Features, Treatment Practices, and Hospital and Long-Term Outcomes of Older Patients Hospitalized with Decompensated Heart Failure: The Worcester Heart Failure Study. *J Am Geriatr Soc*. 2009
16. Hutt E, Frederickson E, Ecord M, Kramer AM. Associations among processes and outcomes of care for Medicare nursing home residents with acute heart failure. *J Am Med Dir Assoc*. 2003; 4:195–9. [PubMed: 12837140]
17. Gaggin HK, Mohammed AA, Bhardwaj A, et al. Heart failure outcomes and benefits of NT-proBNP-guided management in the elderly: Results from the prospective, randomized ProBNP

- outpatient tailored chronic heart failure therapy (PROTECT) study. *J Card Fail.* 2012; 18:626e634. [PubMed: 22858078]
18. Pigone M, DeWalt D, Sheridan S, et al. Interventions to improve health outcomes for patients with low health literacy: A systematic review. *Gen Intern Med.* 2005; 20:185e192.
 19. Kemp E, Floyd M, McCord-Duncan E, Lang F. Patients prefer the method of “tell back collaborative inquiry” to assess understanding of medical information. *JABFM.* 2008; 21:24e30. [PubMed: 18178699]
 20. Hernandez AF, Greiner MA, Fonarow GC, et al. Relationship between early physician follow-up and 30-day readmission among Medicare beneficiaries hospitalized for heart failure. *JAMA.* 303:1716–22. [PubMed: 20442387]
 21. Green CP, Porter CB, Bresnahan DR, Spertus JA. Development and evaluation of the Kansas City Cardiomyopathy Questionnaire: a new health status measure for heart failure. *J Am Coll Cardiol.* 2000; 35:1245–55. [PubMed: 10758967]
 22. Spertus J, Peterson E, Conard MW, et al. Monitoring clinical changes in patients with heart failure: a comparison of methods. *Am Heart J.* 2005; 150:707–15. [PubMed: 16209970]
 23. Afilalo J, Karunanathan S, Eisenberg MJ, Alexander KP, Bergman H. Role of frailty in patients with cardiovascular disease. *Am J Cardiol.* 2009; 103:1616–21. [PubMed: 19463525]
 24. Chaves PH, Semba RD, Leng SX, et al. Impact of anemia and cardiovascular disease on frailty status of community-dwelling older women: the Women’s Health and Aging Studies I and II. *J Gerontol A Biol Sci Med Sci.* 2005; 60:729–35. [PubMed: 15983175]
 25. Fried LP, Tangen CM, Walston J, et al. Frailty in older adults: evidence for a phenotype. *J Gerontol A Biol Sci Med Sci.* 2001; 56:M146–56. [PubMed: 11253156]
 26. Klein BE, Klein R, Knudtson MD, Lee KE. Frailty, morbidity and survival. *Arch Gerontol Geriatr.* 2005; 41:141–9. [PubMed: 16085065]
 27. Woods NF, LaCroix AZ, Gray SL, et al. Frailty: emergence and consequences in women aged 65 and older in the Women’s Health Initiative Observational Study. *J Am Geriatr Soc.* 2005; 53:1321–30. [PubMed: 16078957]
 28. de Vries NM, Staal JB, van Ravensberg CD, Hobbelen JS, Olde Rikkert MG, Nijhuis-van der Sanden MW. Outcome instruments to measure frailty: a systematic review. *Ageing Res Rev.* 10:104–14. [PubMed: 20850567]
 29. Rockwood K, Abeysondera MJ, Mitnitski A. How should we grade frailty in nursing home patients? *J Am Med Dir Assoc.* 2007; 8:595–603. [PubMed: 17998116]
 30. Studenski S, Perera S, Patel K, et al. Gait speed and survival in older adults. *JAMA.* 305:50–8. [PubMed: 21205966]
 31. Boxer RS, Wang Z, Walsh SJ, Hager D, Kenny AM. The utility of the 6-minute walk test as a measure of frailty in older adults with heart failure. *Am J Geriatr Cardiol.* 2008; 17:7–12. [PubMed: 18174754]
 32. Chaudhry SI, McAvay G, Chen S, et al. Risk factors for hospital admission among older persons with newly diagnosed heart failure: findings from the cardiovascular health study. *Journal of the American College of Cardiology.* 2013; 61:635–42. [PubMed: 23391194]
 33. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis.* 1987; 40:373–83. [PubMed: 3558716]
 34. de Groot V, Beckerman H, Lankhorst GJ, Bouter LM. How to measure comorbidity a critical review of available methods. *J Clin Epidemiol.* 2003; 56:221–9. [PubMed: 12725876]
 35. Gortner SR, Jaeger AA, Harr J, Miller T. Elders’ expected and realized benefits from cardiac surgery. *Cardiovasc Nurs.* 1994; 30:9–14. [PubMed: 8137373]
 36. Kiely DK, Bergmann MA, Murphy KM, Jones RN, Orav EJ, Marcantonio ER. Delirium among newly admitted postacute facility patients: prevalence, symptoms, and severity. *J Gerontol A Biol Sci Med Sci.* 2003; 58:M441–5. [PubMed: 12730254]
 37. Kiely DK, Marcantonio ER, Inouye SK, et al. Persistent delirium predicts greater mortality. *J Am Geriatr Soc.* 2009; 57:55–61. [PubMed: 19170790]
 38. Marcantonio ER, Kiely DK, Simon SE, et al. Outcomes of older people admitted to postacute facilities with delirium. *J Am Geriatr Soc.* 2005; 53:963–9. [PubMed: 15935018]

39. McAvay GJ, Van Ness PH, Bogardus ST Jr, et al. Older adults discharged from the hospital with delirium: 1-year outcomes. *J Am Geriatr Soc.* 2006; 54:1245–50. [PubMed: 16913993]
40. Akaike H. A new look at the statistical model identification. *IEEE Transactions on Automatic Control.* 1974; 19:716–23.
41. Albert JM, Wang W, Nelson S. Estimating overall exposure effects for zero-inflated regression models with application to dental caries. *Statistical methods in medical research.* 2011
42. Allen LA, Hernandez AF, Peterson ED, et al. Discharge to a Skilled Nursing Facility and Subsequent Clinical Outcomes Among Older Patients Hospitalized for Heart Failure. *Circ Heart Fail.* 2011
43. Hunt SA, Abraham WT, Chin MH, et al. 2009 focused update incorporated into the ACC/AHA 2005 Guidelines for the Diagnosis and Management of Heart Failure in Adults: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines: developed in collaboration with the International Society for Heart and Lung Transplantation. *Circulation.* 2009; 119:e391–479. [PubMed: 19324966]
44. Ahmed A. Quality and outcomes of heart failure care in older adults: role of multidisciplinary disease-management programs. *Journal of the American Geriatrics Society.* 2002; 50:1590–3. [PubMed: 12383160]

Figure 1.
The HF-DMP in Skilled Nursing Facilities

Table 1**Inclusion and Exclusion Criteria****Inclusion Criteria**

A HF diagnosis is listed as the hospital discharge primary or secondary diagnosis.

Exclusion Criteria

Patients with a life threatening condition which predicts mortality in 6 months.

Patients who are admitted to the hospital from a long term care facility.

Patient with cognitive impairment and no POA/caregiver

End-stage renal disease with dialysis

Table 2

Trial End Points

Primary End Point	<ul style="list-style-type: none"> • Composite all-cause Hospitalizations, emergency department visits, mortality (at 30 and 60 days post-SNF admission)
Secondary Endpoints	<ul style="list-style-type: none"> • Composite CV hospitalizations, emergency department visits, mortality (at 30 and 60 days post-SNF admission) • Heart Failure hospitalization (30 and 60 days post SNF admission) • Total number of all-cause hospital admissions and ED visits from baseline to 60 days post SNF admission • Change in health status (KCCQ) at 60 days • Change in HF self-management (SCHFI) at 60 days • Residential nursing home admission at 60 days • Cost-Effectiveness of HF-DMP