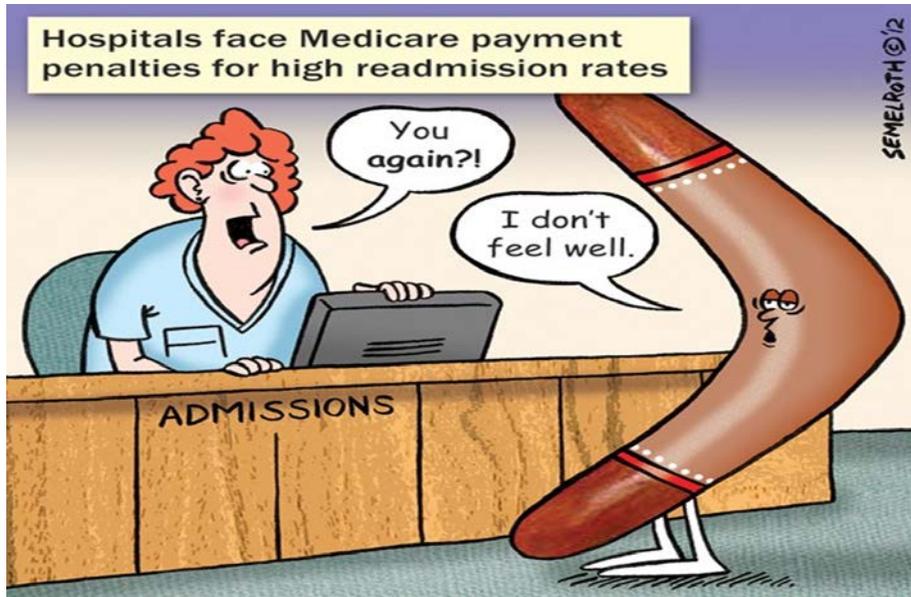


**A WHITE PAPER ON  
CREATION HEALTH PRINCIPLES AND STRATEGIES APPLICABLE TO MODIFYING THE  
RISK FOR HEART FAILURE HOSPITALIZATION AND READMISSION**



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## Introduction

Heart failure (HF) is a chronic and progressive condition in which the heart muscle is unable to pump enough blood to meet the body's need for blood and oxygen.<sup>1</sup> Placement into Class I, Class II, Class III, or Class IV of the New York Heart Association (NYHA) Functional Classification depends on the severity of patient symptoms and how limited they are during physical activity.<sup>1</sup> HF is a leading cause of hospitalization and health care costs in the United States. Nearly 5.1 million people in the United States have been diagnosed with HF, and approximately half of all individuals who develop HF die within five years of diagnosis.<sup>2-3</sup> The total costs of HF to the nation, in terms of direct medical costs and lost productivity, are estimated to be \$32 billion annually.<sup>2-3</sup> Readmission for congestive HF is the most common reason for readmission among Medicare fee-for-service patients,<sup>4</sup> and up to 25% of patients hospitalized with HF are readmitted within 30 days.<sup>5</sup> An analysis of Medicare claims data from 2007 to 2009 discovered that 35% of readmissions within 30 days were for HF, while the remainder of readmissions were for various reasons, such as renal disorders, pneumonia, and arrhythmias.<sup>5</sup> Section 3025 of the Affordable Care Act added section 1886(q) to the Social Security Act, which established the Hospital Readmissions Reduction Program (HRRP). As of October 1, 2012, this program requires the Centers for Medicare and Medicaid Services to decrease reimbursements to hospitals with excessive risk-standardized readmissions.<sup>6</sup> This program encourages hospitals to develop interventions to reduce the readmission rates for HF patients. CREATION Health involves the eight guiding principles of choice, rest, environment, activity, trust, interpersonal relationships, outlook, and nutrition for the delivery of patient care at Florida Hospital. These principles are usually considered to be positive and desirable facilitators of the healing process, but there is a lack of clinical evidence to support this claim.

## Research Questions

In a search for the causal mechanisms for enhancing patient care outcomes, this investigation explored how scientific literature has documented the moderating influence of varying care management principles on hospital outcomes of HF patients. A systematic review of intervention strategies related to CREATION Health was conducted, and a broad range of intervention types aimed at reducing HF readmissions was included. The systematic review and analysis aimed to answer the following specific research questions:

1. What are proofs of the CREATION principles that may modify the care management effects on HF rehospitalization?
2. What do we learn from the empirical evidence-based review about the impact of each CREATION principle on patient care, specifically for HF hospital readmission?
3. Does a single principle work more effectively than a combination of multiple principles in care management for HF patients?
4. How can the knowledge gained from the systematic review and meta-analysis be applied in population health (disease) management for HF?

## Methodology

### Systematic Review

Appropriate keywords were identified related to the (1) independent variable of hospitalization and treatment, (2) the mediating/moderating variable of CREATION principles, (3) the dependent variable of readmission, and (4) the disease of HF. Keyword combinations with one keyword from each of the four categories were used to conduct searches in nine different databases.

Specific inclusion and exclusion criteria were developed in regard to populations, interventions, outcomes, the timing of outcome measurements, time period, settings, publication language, design, and publication format. Only prospective studies associated with HF hospitalization and readmissions,

published in English, Chinese, Spanish, and German journals between January 1, 1990 and August 31, 2015 were compiled. The final selection included 115 studies out of 17,710 reviewed.

### Meta-Analysis

This meta-analysis determined the odds of a HF patient not being readmitted to a hospital. Data were collected from 69 of the 115 studies that met strict criteria based on intervention categories and outcome measures. The intervention groups with the CREATION principles applied in the cited studies were compared with the control groups. The 69 studies were stratified into subgroups based on the combination of CREATION principles in an intervention.

A positive modifying effect was defined as the likelihood of HF patients not being readmitted to the hospital. The odds ratio (OR) represented the odds of successfully avoiding HF readmissions, given exposure to an intervention incorporating one or more CREATION principles. If the OR was 1, it suggested that no difference in the intervention effect with a single principle or combination of principles was found between the treatment (intervention) group and the control group. Thus, a higher OR indicated a higher likelihood of not being readmitted. A p-value less than 0.05 indicated a statistically significant odds ratio with confidence at 95%. In these cases, a researcher is 95% confident that the statistic is correct and not attributable to wrongly accepting an alternative hypothesis by chance.

### **Results of the Systematic Review**

The included studies were published between 1993 and 2015. The interventions occurred in 21 different countries. Fifty-five interventions were implemented in the United States. In terms of sample size, 69 studies had 100 or more participants, and 45 studies had between 20 and 99 participants. Only one study had fewer than 19 participants. The timing of the outcome measure of readmission occurred within one year of hospitalization in 106 studies. Readmission was measured between one year and two years for eight studies. Only one study measured readmission more than two years after hospitalization. Seventy-eight interventions were conducted at a single site, while 37 interventions were conducted at multiple sites. Eighty-two studies were designed as a randomized controlled trial or a randomized trial without a control group. The interventions were grouped by their combinations of CREATION principles. The empirical evidence provided by the systematic review is summarized in this section.

### Choice

Twelve studies incorporated the “Choice” principle.<sup>7-18</sup> In nine of these studies, readmissions were significantly lowered. The interventions that significantly reduced readmissions included:

- Patient education during hospitalization and post-discharge telemonitoring for reinforcement of education and assessment of patients,<sup>12</sup> or post-discharge home visits and monthly calls for reinforcement, assessment, and medication compliance<sup>7</sup>
- Phone calls after discharge for patient education, assessment of symptoms and compliance, and review of medication adherence<sup>13</sup>
- Post-discharge patient education at outpatient clinics, assessment of symptoms and compliance during clinic visits<sup>11</sup> or during follow-up calls every two to four weeks<sup>15</sup>
- Home visit one week after discharge to provide patient education and assess medication adherence and/or symptoms<sup>18</sup>
- Post-discharge assessments of medication adherence, symptoms/health, and compliance through a single home visit one week after discharge,<sup>17</sup> through daily telemonitoring and outpatient clinic visits every one to two weeks,<sup>10</sup> and through a daily telemonitoring system<sup>8</sup>

### Rest

The systematic review did not identify any studies that incorporated the “Rest” principle as a single principle. However, it was included in combinations with other principles.

### Environment

No studies incorporated the “Environment” principle as a single principle or in a combination of principles. However, experimental studies have incorporated an integrated approach to body, mind, and spirit principles into hospital interior design. The subjective assessments show that the healing environment is an important structural component of hospital construction.<sup>19</sup>

### Activity

Four studies incorporated the “Activity” principle.<sup>20-23</sup> In all four studies, readmissions were significantly lowered. The interventions that significantly reduced readmissions included:

- Home-based program of light aerobic exercise and resistance training with home visits by a nurse to assess adherence for 12 months<sup>21-22</sup>
- Aerobic exercise training for 36 supervised sessions followed by home-based training<sup>23</sup>
- Exercise using a cycle ergometer two to three times per week for one year<sup>20</sup>

### Trust

The systematic review did not identify any studies that incorporated the “Trust” principle as a single principle or in a combination of principles.

### Interpersonal Relationships

Two studies incorporated the “Interpersonal Relationships” principle.<sup>24-25</sup> In these studies, readmissions were not significantly lowered.

### Outlook

Two studies incorporated the “Outlook” principle.<sup>26-27</sup> In these studies, readmissions were not significantly lowered.

### Nutrition

Three studies incorporated the “Nutrition” principle.<sup>28-30</sup> In two of these studies, readmissions were significantly lowered. The interventions that significantly reduced readmissions included:

- A comparison of two groups, one with a low sodium diet and the other with a medium sodium diet. Both groups had 1,000 mL/d fluid restriction and a high dose diuretic dose. The group with the medium sodium diet showed a significant reduction in readmissions<sup>29</sup>
- Eight different combinations of levels of fluid intake restriction, sodium intake, and diuretic dosages. A normal sodium diet with high diuretic doses and fluid intake restriction was most effective in reducing readmissions<sup>30</sup>

### Choice and Activity Combined

Two studies incorporated these two principles.<sup>31-32</sup> In one of these studies, readmissions were significantly lowered. The intervention that significantly reduced readmissions included:

- Patient education during hospitalization and post-discharge assessment of symptoms and compliance with emphasis on activity and treatment through internet-based monitoring three times per week<sup>31</sup>

### Choice and Interpersonal Relationships Combined

Five studies incorporated these two principles.<sup>33-37</sup> In two of these studies, readmissions were significantly lowered. The interventions that significantly reduced readmissions included:

- Tools and support for patients and caregivers to encourage active participation in transition from hospital to home using a printed Personal Health Record, and a series of visits and calls with a transition coach emphasizing self-management and direct communication between patient/caregiver and primary care<sup>35</sup>

- Post-discharge education and counseling for patients and families to influence medication adherence through outpatient clinic visits and phone calls focused on incorporating significant others and building positive medication-taking behaviors<sup>37</sup>

#### Choice and Outlook Combined

Only one study incorporated these two principles.<sup>38</sup> In this study, readmissions were not significantly lowered.

#### Choice and Nutrition Combined

Thirty studies incorporated these two principles.<sup>39-67</sup> In 16 of these studies, readmissions were significantly lowered. The interventions that significantly reduced readmissions included:

- Patient education during hospitalization, and weekly or biweekly phone calls after discharge to reinforce education and assess symptoms, compliance,<sup>64-65</sup> and medication adherence<sup>47,60</sup>
- Diet and self-care education during hospitalization, and reinforcement of education and assessment of symptoms and compliance after discharge through weekly calls for two weeks,<sup>44</sup> weekly calls for 12 weeks and two clinic visits,<sup>55</sup> or calls and clinic visits tailored to individual patient needs<sup>57</sup>
- Diet, disease, and drug therapy education at discharge and after discharge on monthly phone calls, clinic assessments, and using a pill counter<sup>45</sup>
- Post-discharge phone calls weekly or biweekly for patient education<sup>41-42</sup>
- Telemonitoring to assess diet, weight, symptoms,<sup>59</sup> and medication adherence, along with home visits<sup>40</sup>
- Patient education about symptoms and diet at discharge and after discharge over the phone, monthly home visits and a daily diary for assessment of symptoms and compliance<sup>54</sup>
- Post-discharge patient education on HF and diet at outpatient clinics, assessment of symptoms and compliance during clinic visits, and monitoring diet and/or medication adherence on calls<sup>49,66</sup> or through the use of a diary and printed guide<sup>52</sup>

#### Rest and Outlook Combined

Only one study incorporated these two principles.<sup>68</sup> In this study, readmissions were significantly lowered. The intervention that significantly reduced readmissions included:

- Relaxation therapy consisting of relaxation training and music therapy for one hour daily and basic psychological care lasting four weeks<sup>68</sup>

#### Activity and Outlook Combined

Only one study incorporated these two principles.<sup>69</sup> In this study, readmissions were not significantly lowered.

#### Choice, Activity, and Interpersonal Relationships Combined

Only one study incorporated these three principles.<sup>70</sup> In this study, readmissions were significantly lowered. The intervention that significantly reduced readmissions included:

- A cardiac rehabilitation program for 12 weeks with an individualized exercise plan and group-based educational session for study participants and their families<sup>70</sup>

#### Choice, Activity, and Nutrition Combined

Twenty-two studies incorporated these three principles.<sup>71-92</sup> In 12 of these studies, readmissions were significantly lowered. The interventions that significantly reduced readmissions included:

- Comprehensive patient education during hospitalization and a follow-up call one to two weeks after discharge<sup>78</sup> and at 90 days calling only high-risk patients<sup>74</sup>
- Patient education during hospitalization and post-discharge assessment of symptoms and compliance with emphasis on diet, activity, and treatment through biweekly phone calls<sup>76</sup>

- Comprehensive patient education during hospitalization and post-discharge reinforcement and assessment of symptoms and compliance emphasizing diet, activity, and treatment through home visits at least once weekly for six weeks<sup>72</sup>
- Post-discharge clinic visits and phone calls at six-month intervals to provide patient education and assess symptoms and compliance<sup>88</sup>
- Patient education after discharge during two to five clinic visits and assessment of symptoms, compliance, and medication use through follow-up phone calls<sup>79</sup> or through the use of a diary and/or pill counter,<sup>75</sup> as well as motivational interviewing,<sup>83</sup> or during monthly home visits with follow-up phone calls every 10-15 days<sup>91</sup>
- One home visit during the first two weeks after discharge to provide patient education on self-management, diet, and physical activity and assess medication adherence and/or symptoms,<sup>71</sup> and follow-up phone calls at 3 and 6 months for assessment<sup>87</sup>
- Education on self-care management, diet, and exercise delivered by a multidisciplinary team in a supervised session once a week for 6 weeks with a 1-hour exercise component<sup>80</sup>

#### Choice, Interpersonal Relationships, and Nutrition Combined

Six studies incorporated these three principles.<sup>93-98</sup> In four of these studies, readmissions were significantly lowered. The intervention that significantly reduced readmissions included:

- Post-discharge education sessions that included advice on diet and sodium restriction for patients and caregivers through weekly outpatient clinic visits<sup>94</sup> or coaching phone calls<sup>98</sup>
- Education on HF, diet, and drug therapy for patients and caregivers at discharge and after discharge on monthly phone calls, clinic assessments, and medication checklist<sup>96</sup>
- Development of care plan and patient and caregiver education by multidisciplinary team during hospitalization and weekly home visits to reinforce education and assess symptoms and compliance for nine weeks after discharge<sup>97</sup>

#### Choice, Outlook, and Nutrition Combined

Two studies incorporated these three principles.<sup>99-100</sup> In these studies, readmissions were not significantly lowered.

#### Choice, Rest, Activity, and Nutrition Combined

Only one study incorporated the four principles.<sup>101</sup> In this study, readmissions were significantly lowered. The intervention that significantly reduced readmissions included:

- Pharmaceutical care, education about self-care, drugs, and medication, and one month of self-monitoring diary cards to record medication use, physical activity, diet, and symptoms<sup>101</sup>

#### Choice, Activity, Interpersonal Relationships, and Nutrition Combined

Eight studies incorporated these four principles.<sup>102-109</sup> In six of these studies, readmissions were significantly lowered. The intervention that significantly reduced readmissions included:

- Educational programs in clinics for patients and families<sup>104-105</sup>
- Pre-discharge education on self-monitoring, diet, exercise, and medication and interview of patients and caregivers by nurse, and post-discharge outpatient clinic visits every three months to review performance and introduce strategies to improve treatment adherence and response<sup>102</sup>
- Comprehensive patient education with families or caregivers during hospitalization and post-discharge reinforcement and assessment of symptoms and compliance emphasizing diet, activity, and treatment through clinic visits every three months<sup>107</sup> or clinic visits and phone calls every two to eight weeks<sup>103</sup>
- Home visit once during the first month after discharge for education on self-management, diet, physical activity, and vaccinations for the patient and his/her caregiver, and emphasis on medication adherence by providing a pill organizer<sup>106</sup>

#### Choice, Activity, Outlook, and Nutrition Combined

Three studies incorporated these four principles.<sup>110-112</sup> In one of these studies, readmissions were significantly lowered. The intervention that significantly reduced readmissions included:

- A multidisciplinary disease management program to provide in-person education to patients when enrolled in the intervention and through follow-up, which included outpatient clinic visits and monthly telephone calls, then visits every few months beginning at six months if the patients had stabilized<sup>112</sup>

#### Choice, Activity, Interpersonal Relationships, Outlook, and Nutrition Combined

Nine studies incorporated these five principles.<sup>113-121</sup> In two of these studies, readmissions were significantly lowered. The intervention that significantly reduced readmissions included:

- A telehealth system that combined self-monitoring and motivational support tools in addition to a comprehensive, multidisciplinary HF care program<sup>114</sup>
- Patient education about HF, medication, diet, and activity during hospitalization, at discharge, or after discharge during home visits and on phone calls, which also included assessment of diet, weight, and medication checklist<sup>119</sup>

#### Choice, Rest, Activity, Interpersonal Relationships, Outlook, and Nutrition Combined

Only one study incorporated these six principles.<sup>122</sup> In this study, readmissions were not significantly lowered.

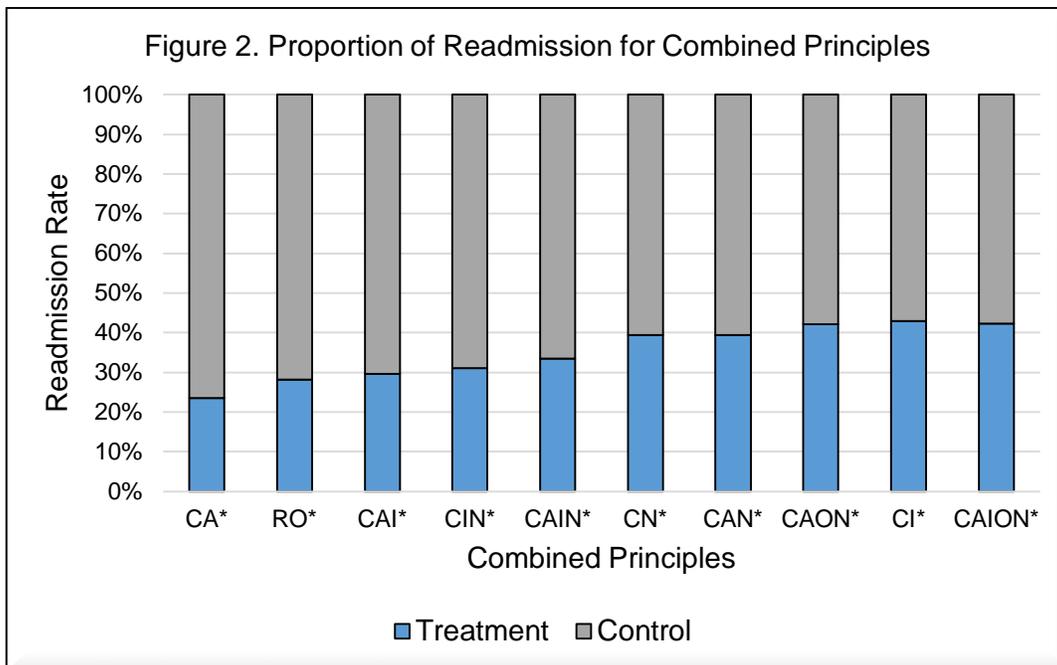
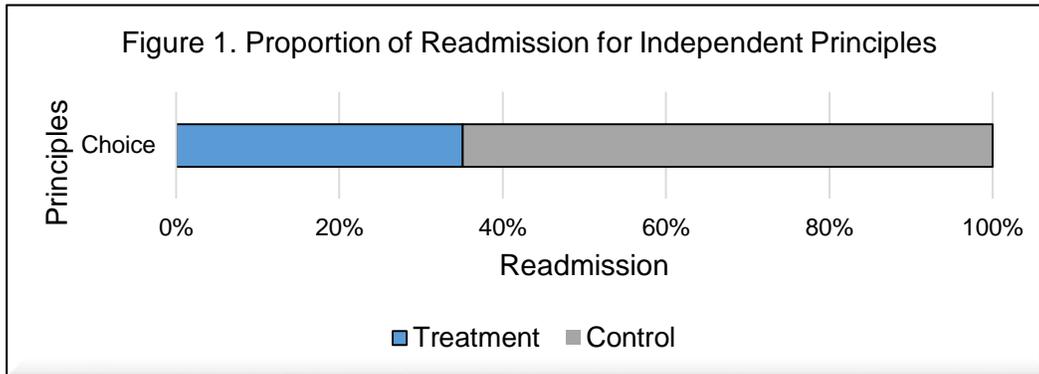
### **Results of the Meta-Analysis**

The above systematic review offers insightful information for guiding the care management practice. In order to get better understanding of the odds for avoiding HF readmission, it is imperative to generate empirical findings that are based on the systematic review. A meta-analysis allowed for the combination of data from several studies to reach a final conclusion about the impact of single or combined CREATION principles in interventions aiming to reduce HF readmissions. The overall odds of being readmitted were approximately 2 times lower among participants of interventions that involved any CREATION principles. The list below shows the likelihood of readmission among participants in a type of intervention: 6.8 times less likely after an intervention involving “Choice”; 3.9 times less likely after an intervention involving “Choice, Activity, and Interpersonal Relationships”; 3.3 times less likely after an intervention involving “Choice and Activity”; 3.0 times less likely after an intervention involving “Rest and Outlook”; 2.5 times less likely after an intervention involving “Choice, Activity, Interpersonal Relationships, and Nutrition”; 2.1 times less likely after an intervention involving “Choice and Nutrition”; 1.8 times less likely after an intervention involving “Choice, Activity, Outlook, and Nutrition”; 1.7 times less likely after an intervention involving “Choice, Activity, Interpersonal Relationships, Outlook, and Nutrition”; 1.6 times less likely after an intervention involving “Choice and Interpersonal Relationships”; 1.6 times less likely after an intervention involving “Choice, Interpersonal Relationships, and Nutrition”; and 1.4 times less likely after an intervention involving “Choice, Activity, and Nutrition.” The subgroups that did not lead to statistically significant reductions in HF readmissions were not listed. These empirical results offer the opportunity to formulate and implement a decision support system for intervening and modifying the odds for undesirable care processes or outcomes, such as hospital readmissions of HF patients, using the known CREATION principles.

#### Summary of Major Findings

The key findings that were statistically significant are shown in the figures below. Figures 1 and 2 show the proportion of readmissions among participants assigned to the treatment groups and control groups in interventions that involved a single principle or a combination of principles as follows:

- Participants in a “Choice” intervention had significantly lower proportions of readmissions when compared to non-participants (Figure 1).
- Participants in interventions incorporating combined principles had significantly lower readmission rates than the control groups. These proportions ranged from 24% to 42% when compared to non-participants (Figure 2).



Figures 3 and 4 show the net reduction in HF hospital readmissions associated with interventions that involved a single principle or a combination of principles of CREATION Health as follows:

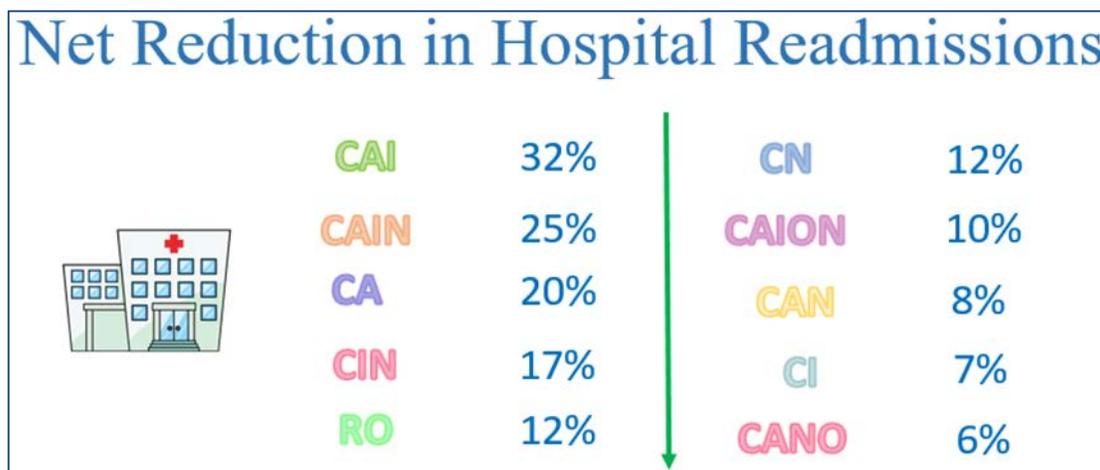
- For the single CREATION principles, interventions with “Choice” as a single strategy yielded a statistically significant net reduction in HF readmissions of 16% (Figure 3).
- Different reduction rates for HF readmission showed that participants in a “Choice + Activity + Interpersonal Relationships” intervention had a reduction rate of 32% and participants in a “Choice + Activity + Interpersonal Relationships + Nutrition” intervention had a reduction rate of 25%, whereas “Choice + Rest + Activity + Nutrition” interventions and “Choice + Outlook” interventions did not yield statistically significant reduction rates for readmissions (Figure 4).

- Participants in interventions with the “Choice” principle in combination with other CREATION principles appeared to show positive benefits in reduction rate for HF readmissions.

Figure 3. Net Reduction in HF Readmissions by Employing Single CREATION Principles



Figure 4. Net Reduction in HF Readmissions by Employing Combined CREATION Principles



### Implications

The implications of the key findings are as follows:

1. The independent and combined effects of “Choice” are the most beneficial strategies to yield a positive benefit to avoid or reduce readmissions of HF patients. The practical implication is that the care management or disease management team could consider a person-centered approach to enhance individual choice or self-efficacy for the patients.
2. “Activity” alone does not yield much beneficial effect, whereas its combination with “Choice” or “Rest” shows greater benefits. This suggests that the clinical team should examine how activities were prescribed, implemented, and evaluated. The lack of adherence or the uncertainty in regard to amounts and types of activities for the therapeutic outcomes may have prevented activities from demonstrating their beneficial effects on readmissions.
3. “Nutrition” by itself shows little beneficial effect. However, its combination with other modifiers or interventions reveals a clear positive effect. Nutritional interventions should be combined with other strategies in order to maximize their optimal benefit in the reduction of risk for HF readmissions.

4. Interventions with CREATION principles increase the likelihood of not being readmitted to the hospital for HF. The meta-analysis results indicate that an intervention involving one or more CREATION principles may nearly double an individual's probability of not being readmitted.

### **Conclusion & Limitations**

This analysis yields robust results that are based on a systematic review and meta-analysis of published clinical trial studies that have met the stringent selection criteria. "Choice" or its combinations with other strategies may show the beneficial effect in reduction of HF readmissions. Although specific favored interventions or CREATION principles on HF readmission are documented, identification of how the mechanism for enhancing "Choice" or patient-centric care modalities is essential to the success for improving care management of HF patients. The limitations of this analysis should be noted, however. First, health education interventions are essential to understand how the **knowledge, motivation, attitude, and preventive practice (KMAP)** in the patient-centered approach may help optimize the beneficial effects or outcomes of CREATION principles. Second, the concepts of "Trust" and "Environment" should be expanded to include broader constructs such as healing environment, artistic expression and art therapy, and interior design of the environment.

Furthermore, we should consider other human factors and information technology that may facilitate patient-provider communications and coordinated care for chronic conditions as the effective care modalities are being developed and implemented for HF care management. There are pilot studies that have shown reasonable effects on hospitalization and readmission. One pilot study of patients diagnosed with HF reports that remote patient monitoring saved \$8,375 per monitored patient annually with a 45% reduction in acute hospital admissions that included a 34% reduction in HF acute hospital admissions.<sup>123</sup>

Overall, this research may help reconfigure the design, implementation, and evaluation of clinical practice for reducing HF readmissions in the future. Because HF is considered an ambulatory, care-sensitive condition, it is imperative to develop coordinated care between the hospital and a patient's primary care physician or network. An appropriately designed decision support system is needed to guide the clinical intervention at the early stage of care management. A hospital-based care management team should be responsible for guiding patients and their caregivers upon hospital discharge. Follow-up procedures for monitoring and evaluating patient outcomes are essential to enhance the process of care or continuous care. Population health management is a broader term of disease management that is applicable to poly-chronic conditions. It is imperative to detect and monitor population health. The knowledge gained from the systematic review and meta-analysis can be applied in population health management for HF through the development of a user-friendly, graphic-user interface (GUI)-based decision support system. The present project is exploring the design and implementation of a GUI-based decision support system to guide the selection of promotion strategies that have demonstrated the efficacy of human factors relevant to CREATION principles for enhancing therapeutic outcomes for HF patients. It will allow a care manager or decision maker identify a variety of modifiers that are amenable to support care processes, improve health outcomes, and avoid hospital readmissions of patients with chronic conditions.

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