CALIFORNIA STATE UNIVERSITY SAN MARCOS  

PROJECT SIGNATURE PAGE  

PROJECT SUBMITTED IN PARTIAL FULFILLMENT  
OF THE REQUIREMENTS FOR THE DEGREE  

MASTER OF SCIENCE  

IN  

NURSING  

PROJECT TITLE: RETROSPECTIVE PILOT STUDY: THE IMPACT OF CHF SPECIFIC  
PRACTICES  

TO DECREASE HOSPITAL 30 DAY READMISSIONS  

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DATE OF SUCCESSFUL DEFENSE: April 7, 2021  

THE PROJECT HAS BEEN ACCEPTED BY THE PROJECT COMMITTEE IN  
PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER  
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RETROSPECTIVE PILOT STUDY: THE IMPACT OF CHF SPECIFIC PRACTICES TO DECREASE HOSPITAL 30 DAY READMISSIONS

A Research Grant Proposal

Presented to the faculty of the School of Nursing
California State University, San Marcos

Submitted in partial satisfaction of the requirements for the degree of

MASTER OF SCIENCE

in
Nursing Family Nurse Practitioner

by
Liliana Montoya

SPRING 2020
Abstract

Hospital readmissions are extensive, expensive, and can overall be avoidable. According to the Centers for Disease Control and Prevention (CDC) (2012), Congestive Heart Failure (CHF) is the second leading cause for hospitalization in the United States. There are about 5.7 million adults in the United States who have been diagnosed and are currently living with CHF (International journal of general medicine, 2018). In California, the average rate of 30-day readmissions for CHF in 2015 was 13.5%. In the facility where I will be conducting my study, CHF’s 30-day readmission rate is 25.4% (Hospital Care Data). This proposed study concentrates on the frequency of CHF readmissions in the acute care setting i.e., a hospital located in Riverside County. This retrospective study aims to improve the 30-day readmission rates of CHF exacerbations. The study will take place over eight months in theory, and the results will be compared to previous CHF readmission rates. The study will compose of implementing education that will be disseminated to readmission patients to prevent further hospitalizations.
Acknowledgements

First and foremost I am extremely grateful to my committee, Dr. Milo and Dr. Boren for their invaluable advice, continuous support, and patience with this grant proposal. Their immense knowledge and plentiful experience have encouraged me in all the time of my academic research and has transcended into my daily life. Finally, I would like to express my gratitude to my family, without their tremendous understanding and encouragement in the past few years, it would be impossible for me to complete my study.
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CHAPTER 1: INTRODUCTION

Hospital readmissions are extensive, expensive, and can overall be avoidable. Hospital readmission is when a patient is admitted into the hospital following an initial hospitalization. The Centers for Medicare and Medicaid Services (CMS) (2010) reports that a standard readmission timeframe is within 30 days of the primary hospitalization. Unfortunately, readmissions are deemed an undesirable clinical outcome because it is suggested that the patient was discharged early from the original hospitalization or that the care received post-hospitalization was substandard.

According to the Centers for Disease Control and Prevention (CDC) (2012), Congestive Heart Failure (CHF) is the second leading cause of hospitalization in the United States. The American Heart Association (AHA) (2017) describes CHF as a chronic progressive condition in which the heart fails to pump the body’s adequate amount of blood. In a comment made in 2013, explains how CHF is trending to be a secondary heart condition related to coronary heart disease, high blood pressure, and diabetes.

There are about 5.7 million adults in the United States who have been diagnosed and are currently living with CHF (International journal of general medicine, 2018). Of those 5.7 million people, there is about 11 million physician visits each year and more hospitalization rates than all forms of cancer combined (Emory Healthcare, 2019). In California, the average rate of 30-day readmissions for CHF in 2015 was 13.5%. In the facility where I will be conducting my study, CHF’s 30-day readmission rate is 25.4% (Hospital Care Data, 2019).

When patients comply with and utilize the diuretics, ACE inhibitors, ARB’s, and Beta-blockers in congruence with obtaining daily weights, following a low sodium diet, exercise, and smoking cessation, the key essentials to living with and managing one’s Heart failure with be
achieved. Unfortunately, CHF is an ongoing disease and will not be cured, however, creating a relationship between the patient and the healthcare team members, successful management, and slow progression of the disease will occur. In turn, fewer hospitalizations will occur, leading to a decrease in readmission rates and cost-effectiveness for the patient, insurance, and hospital.

**Background/ Significance/ Statement of the Problem**

With the increased costs of healthcare and the current shift to preventative care, The *New England Journal of Medicine* (2010) explains that alarming attention has been placed on hospitals because of the unwarranted spending on readmissions. The readmissions and increase in spending could be avoided by improving the quality of care provided in the acute care setting. The Centers for Medicare and Medicaid Services (CMS) (2010) penalizes hospitals for readmissions within the 30 days of discharge. One of the diagnoses that CMS is extremely focused on and is one of CHF’s core measures (Berenson, Paulus, & Kalman, 2012).

According to the *Centers for Disease Control and Prevention* (2019), Heart failure costs the nation an estimated 30.7 billion dollars each year. About half of the aforementioned 5.7 million people who develop CHF die within the five years of being diagnosed. Treating advanced CHF is expensive, but the costs and penalties imposed by CMS for the 30-day readmissions have caused many acute care facilities to assess their current CHF modifiable risk factors that influence care costs.

This proposed study concentrates on the frequency of CHF readmissions in the acute care setting, i.e., a hospital located in Riverside County, as evidence by a decrease of patients that are readmitted to the hospital for CHF exacerbation within 30 days of being discharged home, patients being discharged to a skilled nursing facility are excluded from the study. An area of weakness that attributes to a patient’s readmission is the lack of patient engagement in their care.
It is of extreme importance that education regarding CHF must be enforced, the patient must be engaged, and the patient needs to be able to provide teach back to the Registered Nurse (RN). The Case management advisor (2018) explains that future readmissions can be prevented by providing patients with comprehensive discharge instructions.

The current problem in Riverside County is the lack of resources offered in the clinical setting as the patient transitions from inpatient to home. At this time, discharge paperwork is complete, and educated regarding CHF is provided from the MicroMedex Database. There are missed opportunities for teach-back processes. Follow-up appointments with primary care physicians are often missed, and often patients have difficulty receiving medications due to the inability to pick up prescriptions.

Unfortunately, there is a critical miscommunication between the transition of the hospital to home. These ‘hiccups’ negatively impact the quality of care the patient receives, self-care management, and unavoidable hospital readmissions. With that said, this prompted an extreme need to implement a risk tool such as the LACE tool, discharge checklist, CHF discharge packet, and create follow-up appointments. Once implemented by RN's, these interventions will help identify patients at risk for readmission and overall provide the tools needed to prevent readmission with 30 days of discharge.

**Purpose of Study**

This retrospective study aims to improve the 30-day readmission rates of CHF exacerbations at a local acute care facility in Riverside County. The purpose of this study, CHF exacerbation will be the primary diagnosis indicated in the chart. The high readmission rates and CSM not reimbursing hospital for said readmissions were serious concerns and prompted a need from management to improve the overall quality of care provided.
Implications for Nursing Practice

After being a Registered Nurse on the floor for about four years, patients have indicated two reasons as to why they were readmitted. The primary reason is that the patient did not comprehend the ‘medical jargon’ that was presented. It creates a fault in the Teach-back method. Secondly, the patients’ did not understand which medications they needed to take once discharged and could not schedule a follow-up appointment with their primary physician to sort of confusion, therefore, patients are referred back to pre-hospitalization medication.

A medical center in Southern California is a 324-beds facility. The telemetry unit encompasses 32 of those beds. The study will focus on the telemetry unit and include patients diagnosed with CHF Exacerbations over 18.

Research Question

In patients with CHF exacerbations within the community, there will be a positive impact on implementing CHF specific practices through a decrease in hospital 30-day readmissions as measured by an eight-month post-implementation period when compared to the current approach (no CHF specific practice).

Research Variables

The study's Dependent variable is 30-day readmission into the acute care setting, with the independents variable consisting of special practices that will be implemented. The specific methods will consist of creating pamphlets, providing a measuring cup, scale, and administering a quiz. The demographics will include comorbidities such as chronic obstructive pulmonary disease (COPD) and history of Coronary artery disease, sociodemographic factors including sex, age, and race, and Medical coverage. The study's eligible participants will include patients: ages 18 and older who are discharged home and readmitted to the hospital within 30 days of discharge.
and had the primary diagnosis of CHF exacerbation upon being readmitted. Exclusions include patients discharged to another acute care setting, sub-acute setting, nursing home, or assisted living facility.

**Theoretical Framework/ Conceptual Model**

This study will utilize a retrospective study design because data will be collected at a certain point in time. CHF practices will be placed and disseminated to CHF patients who are readmitted within 30 days of discharge. The study will take place over eight months in theory, and the results will be compared to previous CHF readmission rates. This study will also utilize the Iowa model in certain aspects. The study will compose of implementing education that will be disseminated to readmission patients to prevent further hospitalizations.

**Ethical Considerations**

This study does not involve a vulnerable population in any type of research design. This PI will complete the Collaborative Institutional Training Initiative (CITI) program certification and has filled out the required forms for approval by the California State University San Marcos Institutional Review Board (IRB) (see Appendix for IRB application). This PI will ensure that participants are well informed prior to commencement of the study and have completed an informed consent. The informed consent will outline all the details of the study in easy-to-understand wording. Participants will also be made aware that this study is not meant to provoke any stress, anxiety, or injury, and that withdrawal from the study is permitted at any time. Confidentiality and housing of the participants’ personal information will be maintained throughout the duration of the study on this PI’s password-locked personal computer.
CHAPTER 2: LITERATURE REVIEW

To perform a literature review, databases and search engines were utilized, including CINAHL, PubMed, Google Scholar, and the Institute of Medicine (IOM). The key terms used to find articles included: CHF readmissions, CHF readmissions within 30 days of discharge, CHF rehospitalizations, decreasing CHF readmissions, and causes of CHF readmissions.

Clinical Factors Associated with Readmission

In a 2016 article published in the *Archives of Medical Science*, a retrospective study was conducted in New York City at Harlem Hospital. The study's purpose and aim focused on the causes of CHF readmission within 60 days of discharge. The data collected was over three years with patients meeting criteria of being over the age of 18, ejection fraction <40% as defined by an echocardiogram, Laboratory studies, i.e., biomarkers such as brain natriuretic peptide (BNP), and exhibiting signs and symptoms of CHF exacerbation. A total of one hundred thirty-six readmissions for CHF were identified. A two-sample *t*-test compared early admission and no early admission groups and χ² tests for categorical variables. χ² tests were used to investigate the association between early readmission and clinical factors.

The results yielded significant findings. The clinical factors in the study independently associated CHF readmissions with Latinos and the African- American population. Also, present comorbidities such as Chronic obstructive pulmonary disease (COPD) exacerbate CHF’s progression due to the pathophysiology related to pulmonary hypertension. The strain placed on the right side of the heart impairs cardiac output. The study found that patients with advanced COPD have a 43.9% of early readmission, and patients with a BNP level >1200 had a 25.5% chance of readmission. The Clinical factors presented in the study resulted in an independently significant increased risk of early CHF readmission. Whether they apply to other patient
populations, the clinical characteristics will require additional and prospective investigations for further evaluation.

**Risk factors for 30-day readmissions**

In an article published in *Heart & Lung (2017)*, a retrospective cohort study was conducted over a year in Pennsylvania to identify risk factors for 30-day readmissions in CHF patients. Several patient variables were taken into account, such as comorbidities, demographics, and length of stay in the hospital setting. Mirkin, Enomoto, Caputo, & Hollenbeak (2017) utilized t-tests and logistic regression to identify patient characteristics associated with 30-day readmissions and the differences in patient characteristics in readmission groups. Of the 155,146 patients with CHF, only 35,294 (22.8%) were readmitted within a year. The results indicated that patients discharged to skilled nursing facilities had the highest readmission rates (25.8%) than those discharged to home (19.9%). The study concluded that 30-day readmission rates differed by discharge destination, but risk factors for readmission differed depending on discharge destination. The patients discharged to skilled nursing facilities were more likely to be older than patients discharged to home, with or without home nursing care. The Pennsylvania study clarifies that the discharge destination is a proxy for overall severity and the risk of readmission.

**LACE Index Utilized to Predict the Risk of CHF Patients in Hispanic Population**

In an article published in the *Journal of the American College of Cardiology*, a retrospective study focused on utilizing the LACE tool, which identifies patients at risk for hospital readmission within 30 days. Data was collected from 2012 to 2014, and a total of 94 patients were enrolled. Of said participants, 58 were readmitted into the acute care setting within 30 days. Calderon, Mene-Afejuku, Cativo, Lopez, Garay, Ruiz, & Visco, (2018) stated that the LACE index score was slightly elevated in the readmission group than the non-readmission
group. Still, when comparing high-risk patients vs. low-moderate risk patients, the LACE index did not accurately predict readmissions within 30 days.

**Summary**

The studies presented highlight the complicated, complex, and diverse clinical and social factors that impact CHF patients' early readmission rates. Allocating resources for interventions in patients at particularly high risk for early CHF readmission will be more effective in reducing CHF readmissions, improving patients’ morbidity and mortality, and reducing health care costs while preserving hospital reimbursements.

**CHAPTER 3: METHODS PROPOSAL**

**Introduction**

The *Centers for Medicare and Medicaid Services* (2019) reports that the United States national health expenditures are projected to grow 4.8 percent in 2019, increasing from 4.4 percent growth in 2018, and is expected to reach $3.8 trillion. While new treatments have emerged that ultimately contributed to improved health, certain healthcare system aspects are still plagued with faults. The *Healthcare Cost and Utilization Project* (HCUP) (2016) reports that hospital readmissions are essential for improving care coordination and producing an increase in funds. Unplanned hospital readmissions are deemed too poor health management, poor health outcomes and currently account for $15 to $20 billion annually (Quantros, 2017). Congestive Heart Failure has one of the highest readmission rates in the nation (*EGEM*, 2016). This study aims to evaluate the power of CHF specific implementing techniques that will affect and contribute to lower 30-day readmission rates in underserved community hospitals in Riverside County.
Purpose of the Research

A city is located in Riverside County and currently has a population of 84,277 with a median income of $37,314 (city-data.com). The purpose of this study is to explore whether implementing CHF specific practices will positively impact hospital 30-day readmissions as compared to the current practice of no CHF specific practices in the Southern California. If the CHF implemented methods decrease 30-day hospital readmissions, the hospital will cut costs regarding readmission rates, improve quality of care, and promote educational tactics for patients and nurses working together.

Research Question/ Directional Hypothesis

The research question focuses on the positive impact that will occur by implementing CHF specific practices compared to the current approach (no CHF specific practice) utilizing a decrease in hospital 30-day readmissions as measured by a six-month post-implementation period.

Hypothesis #1: By implementing CHF specific practices, current hospital readmission rates of 25.4% will decrease to 20%.

Research Design

This study is a descriptive, retrospective, analytic design. Charts will be reviewed from the 2017 to 2018, period and data will be collected regarding CHF diagnosis. The originally collected data of readmissions will be compared to Readmissions once CHF specific practices have been implemented for six months. It will allow the study to measure how effective the interventions are and provide a quantifiable measure to reduce readmission costs.
**Threats to Internal Validity.**

Internal validity is of utmost importance in a study. However, there can be internal threats that can interfere with internal validity. The researcher must consider that if a patient is recurrently admitted more than once within the 30-day time frame, patient must only be accounted for once. The instruments utilized must remain constant and not be manipulated to produce specific results. Lastly, in regards to mortality, the classification will need to be a group that will be reported in the study because it cannot be accounted for readmission. Transparency needs to be upheld in this study for it to be concise.

**Study Limitations**

The study has potential limitations, such as multiple treatment interference with patients who experience various comorbidities. Also, the study sample could not accurately represent the general population. A survey conducted by Riverside county (2018) reported a high incidence of opioid use and high related death according to a study conducted from 2011 to 2015. Therefore, socio-demographic demographics must be outlined. Another limitation of the project is that the 30-day readmission rate's impact will not be readily available until the study is complete. Tracking the performance and consistent data collection is essential for breakthrough and continuous levels of improvement.

**Sample/ Sampling**

As a future nurse practitioner, this study identifies and applies interventions that will help deliver safe and quality care to patients and improve patient outcomes. This study will implement CHF specific practices that will aid in reducing 30-day readmissions. Probability sampling will be utilized because patients diagnosed solely with CHF and readmission of CHF exacerbations will focus on the study. This project will include help from the staff on the Cardiac
unit in the acute care facility. The unit is a 32-bed telemetry unit that houses two patients per room. The nurses on this unit are scheduled to work 12 hours shifts, and there would be no financial incentive for their participation in the project. The manager of the telemetry unit, the nurse manager, and the educational coordinator will mandate the attendance of the nurses to obtain, disseminate and implement CHF specific practices.

In regards to sample size for the comparison of pre and post CHF specific practices that will compare 30-day hospital readmissions, at the moment, the researcher cannot calculate a sufficient number that would constitute and deem a decrease in the current 25.4% CHF readmission. G Power analysis will be utilized in congruence with the LACE Tool to evaluate patients who are high risk to be readmitted and are readmitted. Potentially a sample size for this study could be roughly 200 patients that are readmitted into the hospital in an eight-month period with a standardized effect size of 0.05. The findings of this study are generalizable to Southern California. In order to implement and generalize the CHF specific practices that will be implemented at a hospital, the study will need to yield significant results over an extended period, that is why an eight-month pilot study is proposed.

**Data Collection Process**

There will be a LACE Tool utilized to help identify patients at risk for readmission within the 30-day period (Allscripts, 2016). Allscripts explains that LACE is based on four factors: length of stay, acuity of admission, comorbidities, and emergency room visits. The results are calculated, and the higher the score is, the more likely the patient is to return to the hospital. The researcher will implement CHF specific practices. The practices consist of providing CHF patients with a scale (if one is not already in patients’ possessions), a graduated cylinder to measure exact fluid intake, and CHF simplified education will be provided. Appendix
A shows the template approved by the Manager of Hemet hospital and was obtained from the *Healthcare Financial Management Association* (2015).

**IRB**

The researcher for this proposed study will need IRB approval before this plan can be implemented and carried out in an acute care facility.

**Analysis**

Descriptive statistics will be utilized to analyze the data. Patient variables will include demographics such as age (ordinal), gender (nominal), race (nominal), type of insurance (nominal), laboratory value of elevated BNP >1200 (ordinal), comorbidities (nominal) (such as COPD, and Acute Myocardial Infarction) and income (ordinal) will all be taken into account. The study's inclusion criteria are 18 years and older, admitted to hospital and readmittance with CHF exacerbation within 30 days, and admitted from home. Exclusion criteria are patients transferred over from SNF.

**Coding/ Scoring**

The analytical technique utilized will be the t-test to determine whether there are differences in patient characteristics among readmission groups. Logistic regression will also be applied to model 30-day readmissions after disseminating CHF specific practices. In addition, logistic regression will help identify patient characteristics associated with 30-day readmission in patients diagnosed with CHF and who were discharged to home. The statistical significance for all analyses will be defined as a p-value <0.05.
CHAPTER 4: GRANT ELEMENTS

The final chapter of this proposal will talk about the key elements of the grant proposal. The topics that will be discussed will include final grant selection, budget, and budget justification.

Final Proposal: Feasibility

Nearly 1 in 4 patients are hospitalized with heart failure and are readmitted within 30 days of discharge. These rates have been steadily increasing in recent years. Higher readmission rates have been associated with lower patient satisfaction scores and are estimated to cost Medicare more than $17 billion per year in hospital payments. Randomized controlled trials have shown successful efforts to reduce readmissions in a variety of patient populations.

The National Institutes of Health (NIH) intends to prevent disease and promote health through the collection of data in evidence-supported research. Since the NIH recognizes the difficulty to reverse Congestive Heart Failure, the agency has developed a handful of Funding Opportunities that aim to preserve and slow the progression of CHF. Amongst these opportunities is Research Project Exploratory/Developmental Research Grant (R21), funding opportunity PA-11-166, Nutrition and Diet in the Causation, Prevention, and Management of Heart Failure (National Institute of Health, 2014). This research grant allows up to $275,000 in funding for a two-year project (NIH, 2014). The Research Project Exploratory/Developmental Research Grant (R21) grant opportunity opened on March 17th, 2011, and closed on May 8th, 2014 (NIH, 2014). The purpose of this funding opportunity is to encourage the submission of exploratory or developmental research applications on the role of nutrition and diet in the causation, prevention, and treatment of cardiomyopathies and heart failure. The overall goal is to develop a satisfactory science base for the rational nutritional management of patients in various
stages of heart failure and for preventive approaches in high-risk individuals (NIH, 2014). Amongst the topics to be addressed in this research project grant, PA-11-166, is the need for promoting positive health behavior choices in patients diagnosed with CHF (NIH, 2014). The applicant’s study should target cultural, social factors that include but are not limited to, the food industry, communities, and families. The feasibility of this grant meets certain criteria in regards to my proposed grant, however, overall it is not feasible because my proposed grant encompasses more than a diet.

A second proposed grant was titled Increasing Opportunities in Advanced Heart Failure and Palliative Care Research (R01) (NIH, 2011). The purpose of this grant research, RFA-NR-11-006, was to explore the complex needs of advanced HF patients. The study examined the medical, physical, and psychosocial relationships between disease status, symptoms, psychological issues, functional conditions, and spiritual concerns. From there, a plan was developed and tested appropriate palliative care interventions for those with advanced HF and their caregivers. The grants Direct cost per year was $300,000 and not to exceed 4 years. The feasibility of this proposed study would not be agreeable with my proposed CHF study. The aforementioned study focuses on palliative care, this writer’s grant does not focus on palliative care.

The last grant provided, proposed by the NIH in 2010, PA-07-355, titled Improving Heart Failure Disease Management (R01), focused on identifying and improving and disseminating clinically effective disease management tools into clinical practice to reduce HF morbidity and mortality and improve patient outcomes. This research grants R01 allows up to $250,000 per year in direct costs (NIH, 2010). The evidence provided will accumulate evidence from a number of mostly small, short-term randomized trials over the past decade suggests that certain
approaches to HF management may be effective in certain healthcare settings and with certain patient populations, compared with usual care, in reducing hospitalizations and costs. Such approaches include HF-specific clinics, regular nurse phone calls to patients, a variety of home patient monitoring systems, and combinations thereof. Few studies have addressed longer term outcomes or mortality. This proposed grant mimicked my proposed by implementing CHF education to increase patient outcomes.

**Final Grant Selection and Feasibility**

Upon the literature review provided, it is suggested that a substantial proportion of readmissions might be avoidable. This research grant allows up to $25,000 in funding for an eight-month project. The purpose of this funding opportunity is to implement strategies recommended to reduce CHF readmission rates which would include improved patient educational tools regarding their diet, lifestyle, medications, patient-centered discharge instructions, and increased coordination with outpatient providers.

The purpose of this funding opportunity is to encourage patients to follow educational resources provided to positively influence one’s life and overall decrease hospital readmissions. The aforementioned studies reviewed uncovered strengths and weaknesses that this proposed grant can help change. The reviewed journals, grants, and studies created far more questions than answers. This proposed grant will help answer if implementing CHF packets will overall decrease hospital readmissions.

**Budget and Justification**

The study will span over eight months and include the lead RN to prepare and implement the study. Liliana Montoya, RN, will serve as the primary investigator (PI) on this novice study regarding the application of Congestive Heart Failure education to overall decrease readmission
rates. Liliana has been practicing as a Registered Nurse for six years, working in the Intensive Care Unit (ICU) and Telemetry unit. She is currently enrolled in the Family Nurse Practitioner program at California State University San Marcos, where she has researched and developed the proposed study. Liliana will seek help from her research chair advisor Dr. Milo to ensure her study is executed efficiently and accurately. As the PI, Liliana will play a predominant role in recruiting participants, collecting data, analyzing data, and acting as the general coordinator of the study. Liliana will allocate 30% of her time to the proposed research study, therefore requesting $5,000 over the entire study period.

Dr. Milo will serve as the advisor for this proposal. Dr. Milo is a professor at California State University San Marcos, School of Nursing, and a Family Nurse Practitioner. As an advisor, she will provide essential mentoring for the PE to ensure completion of the study. Dr. Milo will allocate 8% of her time or 80 hours of assistance at $100 per hour for a total of $8,000 for the entire grant.

A statistician will serve as an essential consultant member to the research team, leading to the initial coding of the demographic data, inputting data throughout the study into the SPSS 21.0 analysis software, and assisting in final data analysis and interpretation. The ideal applicant is yet to be determined, will be at least a masters-prepared statistician with experience in the statistical analysis of data in research studies. The statistician will allocate 10% of their time to this grant proposal or provide 50 hours of service at $75 per hour for a total of $3,750 for the entire proposal.

The educational packets will include CHF teaching upon being admitted into the acute care facility. Upon discharge home, a home weight scale and a triangular graduated cylinder will be provided. The proposed study requires patients to measure intake. Therefore, a triangular
cylinder ($1.00/each x 125) will be provided, weight scale ($8.00/each x 125). The total estimated cost for this equipment, including California tax (7.5%) is $1,209.38 (($8/scale x 125) + ($0.73/scale x 125) + tax = $1,209.38).

A laptop will be needed to keep patient information confidential and safe, and a laptop will be allocated at a rate of $2,000. A wireless printer and ink are necessary to print material, forms, educational brochures, and questionnaires. The estimated cost for this equipment, including 7.5% California tax is $825.60 ($400/wireless printer + ($46/ink color and black and white x 8 = $825.60)).

The SPSS IBM 21.0 software is necessary to run data analyses and be purchased for $1,330/year. A one-year subscription will suffice for the duration of the proposed study. General office supplies: copy paper ($30/case x 10 cases), pencils ($10/pack x 10), pens ($20/box x 10), and folders ($9/box x 5) are all essential items needed to fill out forms, questionnaires and generating folders. The estimated expense for these items is $2,123.13. A table with expenses is provided in Appendix B.

Timeline

The timeline of this study will occur over eight months. Throughout that time, participants will partake in data collection sessions throughout their hospitalizations until discharge. When being released from the acute care facility, participants will follow up with their primary care providers to prevent re-hospitalizations. Participants will be contacted by the PI at 6-week intervals to follow up on the effectiveness of materials provided, granted patients are not re-admitted in that timeframe.
Dissemination Plan

Conferences.

The findings obtained through this grant proposal will be gathered and presented to associations such as The Heart Failure Society of America (HFSA) in hopes of having it presented virtually. Acute care facilities in Riverside County will also host online classes regarding CHF and findings found through the study. Once allowed, Acute care facilities can host classes but till then, the dates and times will be determined.
References


"Improving Heart Failure Disease Management (R01)." National Institutes of Health, 5 Apr. 2010, National Institutes of Health (grants.nih.gov/grants/guide/pa-files/PA-07-355.html).

"Increasing Opportunities in Advanced Heart Failure and Palliative Care Research (R01)." National Institutes of Health, 2 June 2011, National Institutes of Health (grants.nih.gov/grants/guide/rfa-files/RFA-NR-11-006.html).


Rate of Unplanned Hospital Readmissions Within 30 Days of Discharge (2019, April 26).

In *Let's get healthy california*. Retrieved April 25, 2019, from Lets Get Healthy
(https://letsgethealthy.ca.gov/goals/redesigning-the-health-system/reducing-hospital-readmissions/)


Appendix A

(Healthcare Financial Management Association, 2015)
**NURSING: HEART FAILURE PATIENT TEACHING CHECKLIST**

**Admission and Duration:**
Your doctor has documented that you have heart failure. It is important to know your symptoms and how to manage yourself. We would like to go over some important information:

1. Heart failure overview and smoking cessation

2. Call MD: Weight management and what to do if symptoms worsen.
   a. Weight gain of more than 2 or 3 lbs in one day.
   b. Increase in shortness of breath.
   c. Increase in leg swelling.

3. Review medication related to heart failure and potential for adverse reactions.

4. Diet/fluid restrictions (review and provide a copy of the "Sodium and Fluid Restrictions for Heart Failure" handout).

5. Activity and exercise level (do you have any questions about your activity level?)

6. See discharge instruction sheet for MD follow-up scheduled appointment.

<table>
<thead>
<tr>
<th>Patient signature:</th>
<th>Date:</th>
<th>Time:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guardian signature &amp; relationship:</td>
<td>Date:</td>
<td>Time:</td>
</tr>
<tr>
<td>RN signature &amp; instructed by:</td>
<td>Date:</td>
<td>Time:</td>
</tr>
</tbody>
</table>

**Note:** Signature acknowledges that the patient and or guardian has received and understands the information provided in the above checked teaching checklist.
**NURSING TEACH-BACK QUESTIONS TO VALIDATE HEART FAILURE EDUCATION: DO EACH SHIFT.**

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Initial</th>
<th>Barriers to Learning</th>
</tr>
</thead>
</table>

### ADMISSION

<table>
<thead>
<tr>
<th>Patient</th>
<th>Caregiver</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

- START Heart Failure Tool kit
- Smoking Cessation
- Complete Patient Teaching Checklist (Exit care)

### HEART FAILURE / SYMPTOMS / NOTIFICATION PARAMETERS (CORE MEASURE)

<table>
<thead>
<tr>
<th>Patient</th>
<th>Caregiver</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

- DVD Overview: Heart Failure
- Tell me in your own words what the words “heart failure” mean to you.
- Tell me which heart failure symptoms you remember.

#### Optional Questions You May Ask

<table>
<thead>
<tr>
<th>Patient</th>
<th>Caregiver</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Tell me the symptoms you would call in to your doctor or healthcare provider.
- How will eating too much salt make your symptoms worse?

### DAILY WEIGHTS / DRY WEIGHT / ACTIVITY (CORE MEASURE)

<table>
<thead>
<tr>
<th>Patient</th>
<th>Caregiver</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Do you have a scale at home?
- Tell me how you will weigh yourself each day?
- When will you notify your doctor/provider?
- Tell me how you would know if you are pushing too hard when doing activities?

#### Optional Questions You May Ask

<table>
<thead>
<tr>
<th>Patient</th>
<th>Caregiver</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Can you recall when to notify your MD regarding your weight?
- Tell me how you will be active at home every day?

### MEDICATION / SALT / FLUID LIMITATION (CORE MEASURE)

<table>
<thead>
<tr>
<th>Patient</th>
<th>Caregiver</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- DVD Overview: Heart Failure Medication
- Name a seasoning to avoid.
- Tell me how you will limit your fluids each day.
- Can you tell me the name of your pill?
- Tell me two foods high in salt.
- Can you tell me two foods high in salt?

#### Optional Questions You May Ask

<table>
<thead>
<tr>
<th>Patient</th>
<th>Caregiver</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Name two frozen liquids that count as fluid.
- Name a side effect of your Beta blocker (BP or heart pill).
- Name a side effect of your ACE inhibitor (BP or heart pill).

### FOLLOW-UP APPOINTMENT / SYMPTOMS (CORE MEASURE)

<table>
<thead>
<tr>
<th>Patient</th>
<th>Caregiver</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- What is your family doctor’s name?
- Tell me the date and time of your scheduled follow-up appointment after discharge.
- Tell me what zone you are in if you have gained 3 lbs and have swelling in your feet today.
- If you are in the green zone, what does this mean?

**Initials**

<table>
<thead>
<tr>
<th>Signature</th>
</tr>
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<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

**Initials**

<table>
<thead>
<tr>
<th>Signature</th>
</tr>
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<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

- If discharge anticipated < 4 days, include next day teaching in plan of care.
- If in-patient > 3 days, restart teaching from Day 1.

(Healthcare Financial Management Association, 2015)
**HEART FAILURE (HF)**

**What is heart failure?**
- Your heart is not pumping blood to the rest of the body like it should.

**What are the signs/symptoms?**
- Short of breath
- Low energy
- Swelling in the ankles, feet, or legs (weight gain)

**Causes of heart failure:**
- Heart attack
- High blood pressure
- Coronary artery disease
- Damaged heart valves

**Related health problems:**
- Severe anemia
- Diabetes
- Emphysema
- Kidney or liver failure
- Irregular heart beat

**Medications:**
- Relax blood vessels
- Strengthen the heart
- Pump with more strength
- Get rid of extra water

**Physical Activity:**
- Normal daily activities if able
- Exercise regularly if able
- Short walks at an easy pace
- Do activities or hobbies that you enjoy
- Rest after activity and meals

**Diet:**
- No more than 1 teaspoon of salt a day
- No more than one 2-liter bottle of liquids
- Low cholesterol
- Avoid or less saturated fats
- Avoid or less trans fat

**Notify your doctor if you have these symptoms:**
- Get tired faster
- Not going to the bathroom (urinating less)
- Trouble breathing
- Chest pain or tightness
- Side effects from your medications
- More than usual swelling in the stomach, ankles, feet, or legs
- Gain more than 3 lbs a day or more than 5 lbs a week

**KEY POINTS TO REMEMBER:**
- Weigh yourself every day and record it on your calendar.
- Stop smoking if you smoke.
- Be aware of your signs and symptoms and know what to do. Call 911, go to the emergency room, or get medical attention if your symptoms become worse.
- Take your medications.
- Eat a healthy low-fat and low-salt diet. Read labels on packages and cans of processed and preserved foods.
- Stay active and do activities within your limits.
- Make and go to your doctor appointments.
- Call the Heart Failure Clinic if you have any questions: [Name, telephone number]

*(Healthcare Financial Management Association, 2015)*
<table>
<thead>
<tr>
<th>DAY</th>
<th>TEACHING POINTS</th>
<th>ANSWERS</th>
</tr>
</thead>
</table>
| DAY 0 | • Heart Failure Admission Educational Tool kit given to patient.  
• Patient signs Patient Teaching Checklist. | • Patient received Heart Failure Tool Kit. |
| DAY 1 | • Explain heart failure.  
• Review symptoms.  
• Symptoms to call MD.  
• Explain salt or sodium makes your body hold on to extra fluid and fluid is heavy, making you gain fluid weight. | • Weak heart, not pumping correctly, etc.  
• Symptoms include SOB, coughing; fluid in lungs, belly, feet, and legs; and tired.  
• 3 lb weight gain overnight or 5-7 lbs in a week.  
• Salt makes me gain weight, have more fluid in lungs, legs and belly. |
| DAY 2 | • ASK THE PATIENT IF THEY HAVE A SCALE.  
• Review steps to weigh daily. Scale must be on a hard surface.  
• This is a review question important to ensure they can recall when to notify MD.  
• Review importance of being active every day. Pace activity and with rest periods.  
• Explain walking plan. | • Weigh every morning before eating, at same time, and in same type of clothes.  
• 2-3 lbs weight gain overnight or 5 lbs in a week.  
• Pace activity, rest in between activity.  
• No extra fluid.  
• Walking plan to slowly increase walking time if no symptoms. |
| DAY 3 | • Discuss limiting salt intake to 2000 mg each day. Remind patient to remove the salt shaker from table and stove, no salt substitutes, pick low-sodium foods, and read labels.  
• Review fluid restriction of 2 liters. Teach about being thirsty and what can be done to combat thirst. Remind about the connection of fluid and weight gain.  
• Review diuretic, ACE, and BB if patient is taking including side effects. Cover medication to avoid such as NSAIDS, antacids, and decongestants. | • Patient states 2000 mg sodium diet, no salt or salt substitutes, remove salt shaker from table, store, etc. Pick low-salt foods, read labels.  
• Limit fluid to 2 liters; frozen items or liquids include ice, jello, soup, popsicles, etc.  
• Tired, low blood pressure or heart rate. Low blood pressure, dry cough, high potassium levels, swelling of tongue, throat, or mouth. |
| DISCHARGE DATE | • Family doctor's name:  
• Date and time of F/U appointment made by pt or caregiver.  
• Review Heart Failure zones. | • Record Date/Time or follow-up Appointment.  
With MD on discharge instruction sheet.  
• Use Heart Failure Zone magnet as a Teach Back Guide. |

*(Healthcare Financial Management Association, 2015)*
**SODIUM AND FLUID RESTRICTIONS FOR HEART FAILURE**

<table>
<thead>
<tr>
<th>Limit sodium to 2,000 milligrams per day (Salt)</th>
<th>This is about the amount of sodium in 1 teaspoon of salt.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Even if you don’t add salt to the foods you eat or when you cook, you may still be getting a lot of sodium in your diet. Most foods that are canned or processed have a lot of salt. Frozen dinners are also high in sodium. Almost all restaurant meals (especially fast-food restaurants) have a lot of sodium.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Use less added salt</th>
<th>High in sodium</th>
<th>Use these instead</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salt</td>
<td>Onion salt</td>
<td>Lemon juice</td>
</tr>
<tr>
<td>Seasoned salt</td>
<td>Garlic Salt</td>
<td>Low-sodium broth</td>
</tr>
<tr>
<td>Soy sauce</td>
<td>MSG</td>
<td>Fresh garlic</td>
</tr>
<tr>
<td>Baking soda</td>
<td>Bouillon cubes</td>
<td>Fresh onion</td>
</tr>
<tr>
<td>Baking powder</td>
<td>Tenderizers</td>
<td>Fresh or dried</td>
</tr>
<tr>
<td>Fish sauce</td>
<td>Teriyaki sauce</td>
<td>Herbs</td>
</tr>
<tr>
<td>Worcestershire sauce</td>
<td></td>
<td>Salt-free herb</td>
</tr>
<tr>
<td></td>
<td></td>
<td>sauce</td>
</tr>
<tr>
<td></td>
<td></td>
<td>and spice</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(like Tabasco)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>mixes (like Mrs. Dash)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Limit canned foods</th>
<th>High in Sodium</th>
<th>Try These Instead:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canned soup</td>
<td></td>
<td>Buy fresh or frozen vegetables</td>
</tr>
<tr>
<td>Canned vegetables</td>
<td></td>
<td>Rinse and drain canned foods, do not use the liquid in the can</td>
</tr>
<tr>
<td>Canned meats</td>
<td></td>
<td>Look for “no salt added” canned foods. Be careful though! Some things labeled “reduced salt” still have a lot of sodium or salt.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Limit processed foods</th>
<th>High in Sodium</th>
<th>Try These Instead:</th>
</tr>
</thead>
<tbody>
<tr>
<td>American cheese</td>
<td>Cottage cheese</td>
<td></td>
</tr>
<tr>
<td>Processed cheese spread</td>
<td>Frozen dinners</td>
<td></td>
</tr>
<tr>
<td>Packaged dinner mixes (like Hamburger Helper)</td>
<td>Instant hot cereal</td>
<td></td>
</tr>
<tr>
<td>Ramen noodles</td>
<td>Flavored rice/pasta mixes (like macaroni and cheese, Rice-a-Roni)</td>
<td></td>
</tr>
<tr>
<td>Lunch meat (bologna, salami)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Limit salted foods</th>
<th>High in Sodium</th>
<th>Try These Instead:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salted crackers</td>
<td>Unsalted chips, pretzels, or crackers</td>
<td></td>
</tr>
<tr>
<td>Salted popcorn</td>
<td>Unsalted nuts</td>
<td></td>
</tr>
<tr>
<td>Salted chips</td>
<td>Sprinkle popcorn with dried herbs</td>
<td></td>
</tr>
<tr>
<td>Salted pretzels</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Salted nuts and seeds</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Limit cured foods</th>
<th>High in Sodium</th>
<th>Try These Instead:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ham</td>
<td>Turkey, chicken, or roast beef in sandwiches</td>
<td></td>
</tr>
<tr>
<td>Hot dogs</td>
<td>Turkey bacon, turkey sausage, and turkey or chicken hot dogs are usually lower in fat. However, many still have a lot of sodium.</td>
<td></td>
</tr>
<tr>
<td>Sausage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Koshered meat</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoked fish</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pickles</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sauerkrout</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Fluid restriction</th>
<th>Use these measurements to help you track fluid intake.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 cup = 8 oz.</td>
<td>4 cups = 32 oz.</td>
</tr>
<tr>
<td></td>
<td>Your provider may limit the amount of liquid you drink each day, including any liquids taken with medications. Drinking too many liquids may force your heart to work harder. Fluids include foods that are liquid at room temperature. Other foods may be high in water/fluids.</td>
</tr>
<tr>
<td></td>
<td>Fluids: Water, juice, ice cubes, coffee, milk, cream, popsicle, soup, tea, soups.</td>
</tr>
<tr>
<td></td>
<td>Foods: Yogurt, pudding, ice cream, sherbet, gelatin (Jell-O), follow-up with high water content (ex. Watermelon)</td>
</tr>
<tr>
<td></td>
<td>Suggestions to help with thirst: Suck on hard candies, lemon slices, use a humidifier, and chewing gum.</td>
</tr>
</tbody>
</table>

*(Healthcare Financial Management Association, 2015)*
<table>
<thead>
<tr>
<th>Type</th>
<th>How Does it Work?</th>
<th>Things to Remember</th>
<th>Symptoms to Call MD</th>
</tr>
</thead>
</table>
| **Diuretics** (water pill)  | Helps to get rid of extra water in your body.                                     | • Take early in the day  
  • Frequently urination and thirst are common                                           | Sudden weight changes, abdominal or muscle cramps, swelling in legs or belly, dizziness.              |
| **Potassium Supplement**    | Replaces potassium that may be lost through water pill.                           | • May cause stomach upset.  
  • Take with food to prevent stomach upset.  
  • Drink a lot of water, avoid caffeinated liquids.                                       | Heartburn, diarrhea, dizziness, weakness or heaviness in the legs, tingling in the hands and feet. |
| **Blood Thinner**           | Helps to prevent clots from forming.                                              | • Do not skip doses.  
  • Keep diet consistent.  
  • Take medication around the same time every day.                                         | Bloody/black stools, coughing up blood, red/dark brown urine, and unusual bruising or bleeding.     |
| **Beta Blockers** (blood pressure / heart pill) | Lowers the blood pressure by slowing heart rate and strengthening your heart. | • Do not stop without calling your doctor.  
  • Check heart rate and write down regularly.                                            | Dizziness, swelling or big weight gain, feeling very tired or weak.                                 |
| **ACE Inhibitor or ARB** (Blood pressure / heart pill) | Lowers blood pressure to help heart pump more easily by relaxing blood vessels | • Check and write down blood pressure regularly.                                      | Dizziness, trouble breathing, cough that doesn’t go away, and fast heartbeat.                        |

*(Healthcare Financial Management Association, 2015)*
### CHF Pilot Budget

**Total**  
$24,228.11

<table>
<thead>
<tr>
<th>Item</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liliana Montoya MSN-C</td>
<td>$5,000.00</td>
</tr>
<tr>
<td>Dr. Milo</td>
<td>$8,000.00</td>
</tr>
<tr>
<td>Statistician</td>
<td>$3,750.00</td>
</tr>
<tr>
<td>Materials</td>
<td>$1,209.38</td>
</tr>
<tr>
<td>Equipment</td>
<td>$825.60</td>
</tr>
<tr>
<td>Personal laptop</td>
<td>$2,000.00</td>
</tr>
<tr>
<td>Office supplies</td>
<td>$2,113.13</td>
</tr>
<tr>
<td>Software</td>
<td>$1,330.00</td>
</tr>
</tbody>
</table>
Appendix C

Exempt Review Application Form

Instructions:
Please fill out this application form using clear language and lay terms. Please answer each section as completely and as concisely as possible. Some questions may not apply to your study. In that case, please add “not applicable” in the text box. Please upload this application form along with additional documents that are supplemental (as applicable) to your submission in IRBNet. For more information, please visit the IRB website. For questions, please contact IRB office at (760) 750-4039 or irb@csusm.edu.

Project Title
RETROSPECTIVE PILOT STUDY: THE IMPACT OF CHF SPECIFIC PRACTICE TO DECREASE HOSPITAL 30 DAY READMISSIONS

Proposed Start Date
August 27, 2022

Faculty/Staff Investigator:
Name: Razel Milo
Phone Number:
Department/College: CSU- San Marcos
E-mail: rmilo@csusm.edu
Date CITI Training Completed: May 18, 2016

Student Investigator: (if the student is the principal investigator)
Name: Liliana Montoya
Phone Number: (951) 500-0999
Department/College: CSU- San Marcos
E-mail: monto031@cougars.csusm.edu
Date CITI Training Completed: September 5, 201

Faculty Advisor Name:
Department/College:
Phone Number:
E-mail:
Date CITI Training Completed:

REMINDER: Once the student investigator has completed this application form, he or she must e-mail it to their faculty advisor for review and feedback. Once the faculty advisor gives permission to the student to move forward, then the student will upload this application form along with additional documents to IRBNet. Once the student uploads all the documents, they will share the IRBNet package with the faculty advisor. The faculty advisor must have an IRBNet account to approve the package as the "advisor" by logging into IRBNet. The faculty advisor will receive a notification via e-mail that the package has been shared with them and that they need to sign the package in IRBNet. For more information on how to share a package in IRBNet, please visit the IRB website.

Checklist: Check the additional documents that are uploaded in IRBNet. Check ALL that apply:

- CITI Training Certificate for the principal investigator and the faculty advisor, if applicable.
- Letter of support (if you are collecting data off campus, you need to provide a letter of support from the research site. The letter of support must include the letterhead of the organization and list the research activities to provide evidence that the organization is knowledgeable about the study).
- Survey(s), questionnaire(s), and/or interview questions. If you are using an online survey, please upload a PDF copy of the survey.
- Ed.D Students in the Joint Doctoral Program Only: Sign, scan, and upload the UCSD-CSUSM JDP IRB Cover Sheet in IRBNet.
### A. Exempt Review Categories

The following categories of research are currently approved for exemption. Please check the relevant exemption category/categories for your study.

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category 1</td>
<td>Research conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, research on the effectiveness of the comparison among instructional techniques, curricular, or classroom management methods.</td>
</tr>
<tr>
<td>Category 2</td>
<td>Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects AND (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.</td>
</tr>
<tr>
<td>Category 3</td>
<td>Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection if (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects AND (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.</td>
</tr>
<tr>
<td>Category 4</td>
<td>Secondary research (study of existing data including documents, records, or biospecimens) for which consent is not required; AND IF (i) The identifiable private information or identifiable biospecimens are publicly available; OR (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; OR (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated for the purposes of &quot;health care operations&quot; or &quot;research&quot; or for &quot;public health activities and purposes;&quot; OR (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities.</td>
</tr>
<tr>
<td>Category 5</td>
<td>Research and demonstration projects which are conducted by or subject to the approval of appropriate Federal Department of Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; OR (ii) procedures for obtaining benefits or services under those programs; OR (iii) possible changes in or alternatives to those programs or procedures; OR (iv) possible changes in methods or levels of payment for benefits or services under those programs.</td>
</tr>
<tr>
<td>Category 6</td>
<td>Taste and food quality evaluation and consumer acceptance studies if the food has been found to be safe by the FDA or other food safety agency.</td>
</tr>
</tbody>
</table>

### B. Please answer the following questions about your research study.

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>My research participants belong to a vulnerable population (e.g. children under 18 years of age if studied outside a normal classroom setting, prisoners, or any other vulnerable population.)</td>
<td>☑</td>
<td>☐</td>
</tr>
<tr>
<td>I will record data from participants in such a way that their identity can be readily ascertained, directly or through identifiers linked to the participants AND any disclosure of participants' data outside of the research could be damaging to them or place them at risk of criminal or civil liability, be socially stigmatizing, or influence employability, financial standing, insurability, access to services, educational advancement, or reputation.</td>
<td>☑</td>
<td>☐</td>
</tr>
<tr>
<td>My research participants will experience some physical, emotional, or mental stress, discomfort, or harm.</td>
<td>☑</td>
<td>☐</td>
</tr>
<tr>
<td>My research involves secondary research where broad consent from research participants will be or has been obtained for collecting, storing, and maintaining identifiable private information or identifiable biospecimens (e.g. saliva, urine, blood, etc.)</td>
<td>☑</td>
<td>☐</td>
</tr>
<tr>
<td>My research involves the deception of participants (meaning participants are not provided with or mislead about the purpose of the research study in the beginning of the study) AND participants will not be prospectively agreeing to participate in a study that contains deception.</td>
<td>☑</td>
<td>☐</td>
</tr>
</tbody>
</table>

If you answered 'yes' to any of the above questions, you need to fill out a limited/expedited or full review application.
If you answered 'no' to ALL questions in Section B AND your research study fits within at least one of the exempt categories in Section A, then proceed to answer the following questions about your research study. Please answer each question thoughtfully.

1. Describe the nature and purpose of your research study, including the significance of your research project and your research questions, and how your study will attempt to answer it. Please include three citations in your description. Do not include methodology in this section.

This proposed study concentrates on the frequency of CHF readmissions in the acute care setting in Riverside County, as evidence by a decrease of patients that are readmitted to the hospital for CHF.

2. Provide a step-by-step explanation of your research activities that involve human subjects including data collection methods and how you will store the data you plan to collect. Be thorough. You must provide enough detail so that the IRB can determine that your research qualifies for exemption.

Charts will be reviewed and data will be collected to assess the perctange of patients readmitted for CHF.

3. For research conducted in established educational settings, please state HOW the research activity (not the instructional material) is a "Normal Educational Practice."

A CHF packet with CHF material such as diet intake, Fluid intake and medication side effects will be provided so patients can understand and manage their disease.

4. For secondary research using biospecimens for which consent is not required, please explain how the identifiable biospecimens are publicly available or data recorded by the researcher such that it is anonymous. Additionally, explain where and how the data is stored and will be disposed.

no biospecimens used

5. Describe the participants that will be involved in your research. How will you be selecting/recruiting your population? Will anyone be excluded from participating? If you have multiple participant groups such as students and teachers or children and parents, please describe each population.

The study's eligible participants will include patients: ages 18 and older who are discharged home and readmitted to the hospital within 30 days of discharge and had the primary diagnosis of CHF exacerbation upon being readmitted. Exclusions include patients discharged to another acute care setting, sub-acute setting, nursing home, or assisted living facility.

6. How many participants will be involved in your research? Provide a quantity for each population group.

per my G power- 84 participants, however it will be based on CHF readmissions

7. Are you employed at the research site where you plan to collect data?  
☐ Yes  ☐ No

8. Briefly outline the principal investigator's qualifications and experiences related to the research study.

The principal investigator's background ranges from being Charge RN on a telemetry unit and currently an ICU RN for 6 years. This Principal investigator's fluent in spanish and can assist patients to better understand their disease and prevent the fast progression of CHF.
9. If the principal investigator is a student, include faculty advisor's qualifications.

Dr. Mio is currently a FNP and instructor at CSUSM.

10. If using student or research assistants, please explain how you will ensure that these assistants are trained and qualified to assist the project including obtaining consent forms and collecting data. All assistants must complete the CITI training before starting to work on the project. It is the faculty member’s responsibility to keep a copy of student assistants’ CITI training certificate on their record.

no research assistant's will be utilized.

11. For Student Principal Investigators Only: Please check the box below to verify that you will share your package and obtain your faculty advisor's signature in IRBNet:

☑ I verify that I will share my package with my faculty advisor in IRBNet after I upload this application and other materials, but before submitting the package for review.

12. Is this project funded externally? ☐ Yes ☐ No

If Yes, please provide the name of the funder:
Appendix D

Demographic Survey Form
Demographic Survey Form

All of the information on this form will be transferred onto a password locked computer and then shredded to protect your privacy. This information will only be used to remind you when meeting days are coming up and to provide an accurate description of the sample population included in the study. Your name and information will always be kept confidential and locked in a secured area.

First Name: ________________________________

Last Name Initial Only: ___

Age: ______

Assigned Sex at Birth:
- Female
- Male
- Would rather not say

Ethnicity:
- White
- Hispanic or Latino
- Black or African American
- Native American or American Indian
- Asian / Pacific Islander
- Other ________________________________
- Would rather not say

Home Phone Number: ______________________

Cell Phone Number: ________________________

Email: ___________________________________
Appendix E

Informed Consent

My name is Liliana Montoya. I am a family nurse practitioner student at California State University San Marcos. I am doing a study that aims to decrease hospital CHF readmissions. You, the “participant” in this letter, is invited to join this study because you meet specific criteria designed by me, the “researcher”.

Requirements of Participation

This study is designed to last 8 months. Throughout that time the participant will be asked to meet with the PCP after discharge home. The PI will conduct weekly phone calls with participants to follow up on care and questions.

Confidentiality & Risks

The participant will not need to provide their address. The participant will give their first name, last name initial, age, height, weight, email address and phone number. A code number will be assigned to the participant’s name so the data collected cannot be directly linked to the participant. All information will be kept in a locked cabinet and a password protected laptop. It is possible others may learn of the participant’s enrollment in the study, however the researcher will make every effort to be as discrete and brief as possible during meetings with the participant. If the participant experiences any negative feelings during the study, supportive resources will be provided; also the participant may leave the study at any time without consequences.

Voluntary Participation

Participation is voluntary. The participant does not have to join the study and may withdraw at any time. The participant will not experience any consequences for deciding not to participate or for leaving the study.

Questions

The California State University San Marcos Institutional Review Board (IRB) will need to approve this study. For any questions I will be happy to answer them now or you may contact me at any time: Liliana Montoya, mont031@cougars.csusm.edu. For questions about the rights of the participant, please contact the California State University San Marcos IRB at 760-750-4029. Keep a copy of this form for your records. Thank you.

☐ I agree to participate in this research study.

______________________________ ___________________________ _______
Signature Date __________________________