Advanced Practice Registered Nurse Led Transitional Care Program in an Accountable Care

Organization

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Abstract

Purpose: Reduce or prevent readmissions among heart failure (HF) patients and increase quality of life (QOL), self-care behavior (SCB) and satisfaction through an advanced practice registered nurse (APRN) led transitional care program (TCP) in collaboration with an Accountable Care Organization (ACO).

Background: Hospital readmissions place a heavy financial burden on patients, families, and health care systems. Readmissions can be reduced or prevented by providing a safe transition through care coordination and enhanced communication. Research demonstrates implementation of APRN led home visits (HV) along with telephonic follow-up are cost effective and can be utilized for reducing readmissions among HF patients.

Methods: A program was designed with an ACO and carried out in a family practice clinic with a group of seven HF patients older than 50 years who were at risk of readmission. Interventions included weekly HV with supplemental telephonic calls by the APRN student along with a physician assistant for 12 weeks. Readmission data was collected. QOL and SCB were measured using "*Minnesota Living with Heart Failure Questionnaire*" (MLHFQ) and "*European Heart Failure Self-Care Behavior Scale*" respectively. Data was analyzed using descriptive statistics and the Friedman Test.

Outcomes: There were no hospital readmissions at 30 days and the interventions demonstrated a positive effect on QOL, self-care management and satisfaction ($\chi^2 = 30.35$, p=.000). The intervention had a large effect on the outcome variables resulting in an increase in QOL and SCB scores post-intervention (ES= -1.4 and -2 respectively).

Conclusions: TCP designed with an ACO, carried out in a primary care setting has a positive effect on reducing hospital readmissions and improving QOL, SCBs, and patient satisfaction

among HF patients. TCPs are not revenue generating at outset due to reimbursement issues, however future considerations of a multidisciplinary team approach with convenient workflow may be explored for long-term feasibility and sustainability.

Funding Source: American Association of Colleges of Nursing and the Centers for Disease Control and Prevention with support of the Academic Partners to Improve Health.

Keywords: Heart failure, Hospital readmissions, Transitional care, Home visits, Telephonic call.

Advanced Practice Registered Nurse Led Transitional Care Program in an Accountable Care Organization

Introduction

Unnecessary or preventable hospital readmissions are a financial burden for the United States healthcare system. Heart failure (HF) is one of the major reasons for readmissions and healthcare costs. Recurrent admissions have an impact on the quality of patients' life, selfmanagement, and functional status; worsens the disease process, renounces hope, and turns into an affliction to the care giver/family. At present, policymakers and health care providers are focused on the goals of improving excellence of care and decreasing hospital readmissions, and the overall cost of care.

Background/Significance

Heart failure patients often do not receive the level of care required for a safe transition from hospital to home, which increases the incidence of readmission, escalates healthcare costs, and reduces quality of life (QOL). Approximately, one in five Medicare beneficiaries is readmitted within 30 days of hospitalization (Shams, Ajorlou & Yang, 2015). These are unplanned hospitalizations and 75% of these admissions could be prevented saving approximately \$17 billion dollars (Shams, Ajorlou & Yang, 2015). In an analysis of Medicare fee-for-service claims data from 2007-2009, the 30-day readmission rate for HF patients was 24.8% (Dharmarajan et al., 2013). As part of discovering innovative ways to reduce total cost per patient, the *Medicare Shared Savings Programs* (Section 3022) was established. In this program, Accountable Care Organizations (ACO) are required to submit performance data related to care transitions and reimbursement is based on quality of care and patient outcomes (Naylor, Aiken, Kurtzman, Olds, & Hirschman, 2011). As part of the data collection and analysis under the Medicare Shared Savings Program (MSSP), an ACO in the southwestern United States (U.S.) has identified a need to improve the hospitalizations and readmission rates. A target practice site was identified as having increased hospital readmissions above the ACO benchmarks. In this site, the total number of Medicare patients is 2077; there were 36 and 40 all-cause readmissions in 2014 and 2015 respectively (Donkerbrook, L., personal communication, March 04, 2016). Currently the office has same day appointments available for sick patients, 24-hour triage line; pre-discharge interviews and post discharge home visit by a case manager to assess needs of the patient within the home setting. With these available resources, there is a communication gap between the provider and the patients. Providers find they are unable to provide continuity of care that the patients need for a safe transition out of the hospital and prevent the incidence of readmission.

Several factors that influence hospital readmissions include lack of access to a primary care provider (PCP), complications during hospitalization, lack of social support, or community resources, poor socioeconomic status, illiteracy, unawareness of disease process, cognitive impairment, co-morbid conditions or underlying disability, poor adherence to medications and treatment plan, medication errors, missed discharge follow up and lack of structured discharge communication (Rennke & Ranji, 2015). Despite having insurance, more than 50% of patients have no contact with their primary care physician between their first hospitalization and their readmission (Kripalani et al., 2007). Due to rising healthcare costs, interventions aimed at preventing HF readmissions, transitional care interventions (TCI) have emerged.

Transitional care interventions. Multiple systematic reviews and meta-analysis concluded that home visiting programs, multidisciplinary HF clinic interventions and telephone

support reduced HF readmissions as well as mortality rates (Feltner et al., 2014; Naylor, Aiken, Kurtzman, Olds & Hirschman, 2011). TCIs including weekly home visits alone for a month or in combination with telephone calls showed an increase in patient's QOL and decrease in the number of readmissions and health care costs among individuals with HF (Courtney et al., 2012; Stamp, Machado & Allen, 2014). According to Vedel and Khanassov (2015), highintensity TCIs (combining home visits with telephone follow-up, clinic visits, or both) reduced HF readmission risk regardless of the duration of follow-up. A systematic review and metaanalysis of 42 randomized control trials concluded that patient education, home visits, selfmanagement support and case management are effective in reducing all cause 30-day readmission rates and improving patient capacity for self-care (Leppin et al., 2014). A quasiexperimental prospective cohort study evaluated the effectiveness of care transitions interventions and appeared to be successful in reducing all cause 30-day readmissions among fee-for-service Medicare patients. The interventions include a coach completing a hospital visit, a home visit and two follow-up telephone calls (Voss, Gardner, Baier, Butterfield, Lehrman & Gravenstein, 2011).

Role of advanced practice registered nurses. Heart failure patients confront challenges in modifying self-care behaviors (SCB) to maintain health. Advance practice registered nurses (APRNs) play an important role in coordinating care and providing education. A systematic review indicated that APRNs provide effective and high quality care to patients (Newhouse et al., 2011). A prospective study completed by Stauffer et al. (2011), found that APRN led TCIs were effective and reported to have a decrease in 30-day HF readmission rates as well as overall cost of care. In an RCT, Brandon, Schuessler, Ellison and Lazenby (2009) evaluated the effect of APN led telephonic intervention on hospital readmissions, QOL and SCBs of HF patients and the results showed a positive impact on outcomes of HF patients by reducing readmissions and improving QOL and SCBs.

Search Strategy

The initial review for an effective intervention has lead to the clinically appropriate PICOT question, "In patients (> 50 years old) with heart failure (**P**), how does weekly home visit with a telephonic follow up by an advanced practice provider (**I**) compare to standard of care (**C**) affect 30-day readmission rates (**O**) over a 12 week period (**T**)?"

An extensive electronic search was performed to retrieve pertinent studies to answer the PICOT question. The databases utilized for this review included Cumulative Index to Nursing and Allied Health Literature (CINAHL), 2005-2015, PubMed, 2011-2016, Cochrane database, and The Joanna Briggs Institute Database of Systematic Reviews and Implementation Reports, 2011-2016. Limits including English language and human subjects were applied to the search. The key words used for the search were *heart failure readmissions, transitional care interventions, transitional care management, home visits, home based interventions* and *advanced practice nurses*. A total of 15 studies were selected for evaluation. From that intitial group, several systematic reviews were excluded due to the similarity of the studies and variables examined. Ten studies relevant to the PICOT question were chosen for critical appraisal and synthesis of evidence.

Synthesis of Evidence

In general, the selected studies were of high quality and included six randomized controlled trials (RCTs) of level II evidence, three systematic reviews of level I, and one prospective study of level III evidence (Melnyk & Fineout-Overholt, 2015). The evidence suggests that TCIs conducted in different settings can have a positive effect on reducing

hospital readmissions, mortality and improving QOL, SCB, cost savings and patient satisfaction among HF patients (Aguado et al., 2010; Biese et al., 2014; Courtney et al., 2012; DeWalt et al., 2006; Feltner et al., 2014; Leppin et al., 2014; Naylor et al., 2004; Stauffer et al., 2011; Wong, Chow, Chan & Tam, 2014). A significant effect is reported when interventions were bundled in the TCP. Home visit together with telephonic follow-up had the greatest effect in reducing readmissions. A significant effect on TCI outcomes was observed with APRN-led interventions. At least eight home visits (once weekly for the first four weeks and once in alternate weeks for next eight weeks) were conducted in two of the studies. The time frame of the interventions for most of the studies was 12 weeks (3 months) but there was no difference in outcomes resulting from differences in length of interventions. Across studies, the instrumentation was valid and reliable. Instrumentation included Instrumental Activities of Daily Living scale, Minnesota Living with Heart Failure Questionnaire, self-efficacy scale, Short Test of Functional Health Literacy in Adults (STOFHLA), European Heart Failure Self-Care Behavior Scale, Short Form -36 questionnaire and Chronic Disease Self-Efficacy Scale.

In conclusion, evidence from this review strongly suggests that implementation of APRN-led home visit along with telephonic follow-up will be cost effective and can be utilized for reducing readmissions among HF patients.

Purpose

The purpose of the project was to develop an APRN led transitional care program (TCP) with an ACO to implement in a family practice clinic to reduce or prevent readmissions among HF patients and increase patients' QOL, SCB and satisfaction.

Evidence Based Practice Model Chosen to Guide Project Development

The *Iowa Model of Evidence-Based Practice to Promote Quality Care* aids clinicians in making decisions that will have an impact on patient outcomes (Titler et al., 2001). This model is known for its applicability and ease of use by multidisciplinary healthcare teams. A team was formed for the TCP that included a physician, physician assistant (PA), pharmacist, case manager and registered nurse who was the co-investigator on the project. The Iowa model was chosen to implement an evidence based practice (EBP) program for reducing readmissions because this model clearly explains the steps for changing a practice and assists users in adhering to the principles of EBP (Appendix A). The steps include identification of a clinical problem, literature review and evidence synthesis, piloting a practice change, evaluation of the pilot and outcomes, and finally dissemination of results (Titler et al., 2001).

Theoretical/Conceptual Framework

Dorothea Orem's Self-Care Theory which highlights the significance of being independent for one's own care (Orem, 2001) and Afaf Meleis's Theory of Transition which provides a guide to moving a patient from one setting to another (Meleis, Sawyer, Im, Messias, & Schumacher, 2000) can inform the design of interventions that improve patient outcomes. According to Orem's theory, a patient's knowledge of health problems is required for improving self-care behaviors (Orem, 2001). The main challenges associated with heart failure patients are lack of knowledge and improper performance of self-care. Current evidence shows that patients who perform self-management behaviors enhance their health outcomes. During the home visit, patient education on self-care behaviors was provided to improve selfcare behaviors and functional status and increase the quality of life. Transition theory was used to help the TCP team to analyze the goals, feelings and behaviors necessary for the patients to adjust to the new situation and transitioning (Smith & Parker, 2015).

Methods

Ethical Considerations

An approval letter including the permission to access the health records was obtained from the Medical Director of the clinical practice (Appendix B). Arizona State University institutional review board approved the project as an Expedited Review (Appendix C). Informed consent was obtained from participants prior to their engagement in the project (Appendix D).

Practice setting and Participants

The project site was a family practice clinic in a metropolitan area in the southwestern U.S. There are three physicians, eleven PAs and a chiropractor. The patients were identified by the clinical site supervising physician or the PA and the project was introduced to the potential participants. Inclusion criteria for patients were age > 50 yrs, English speaking, able to read and write English, Medicare or Medicare Advantage beneficiaries and heart failure patients recently discharged from the hospital or at risk of readmissions. The potential participants were invited by the co-investigator to participate in the project and a group of seven patients was enrolled.

Intervention

In the initial phase, the team formed for the TCP included a physician, PA, pharmacist, case manager and registered nurse/co-investigator. A pharmacy that delivers medications to the home at no extra cost was included in this program to ensure the timely availability of medications. The intervention period was 12 weeks for each participants and patients were

enrolled during the first three weeks of the intervention period. Patients were offered the home delivery pharmacy service; changing their pharmacy was not mandatory. Weekly home visits were conducted by the co-investigator along with the PA for 12 weeks and included physical assessment, vital signs, medication reconciliation or adjustment if needed and patient education on medications, self-care behaviors, and symptom management. During the first visit, patients were provided with education materials, a blood pressure (BP) machine, weighing scale, BP and weight log, pill cutter, pill organizer and a gift card (\$25.00). Patients were encouraged to check their BP, heart rate and weight daily and maintain a log. The initial home visit took approximately one hour and the subsequent visits took an average of 25 minutes. A supplementary telephonic call was made weekly to check on patients, maintain a good relationship, build trust and assure the continuity of care. In addition, participants were provided with a 24-hour triage line and the office number with the extension to the medical assistant of the PA to report any changes. The ACO case manager arranged home health or physical therapy for the patients as needed. The supervising physician was updated weekly by the PA and the co-investigator on patients' status, needs, deficits and services provided. The program effectiveness was evaluated every four weeks by conducting meetings with the TCP physician to evaluate the strengths, weaknesses, flaws and to discuss ways to improve the program based on the evaluation.

Outcome Measures

The primary outcome in this project was the number of hospital readmissions at 30 days post discharge. The secondary outcomes were patients' quality of life, self-care behaviors and satisfaction.

Instruments

A demographic questionnaire (Appendix E) was developed to collect information on patient demographics and information on chronic conditions, HF management, last hospitalization and number of emergency room and hospitalizations in the past six months.

Pre and post intervention QOL was measured using *Minnesota Living with Heart Failure Questionnaire* (MLHFQ) (Appendix F). Permission was obtained from University of Minnesota Office for Technology Commercialization. The MLHFQ is a self-administered questionnaire that has 21 questions rated on a six-point Likert scales with a total score range from 0 to 105 (from best to worst) which represents various degrees of impact of HF on health related QOL (University of Minnesota, 2016). This tool has been evaluated for the applicability, internal consistency, and validity and found high internal consistency with Cronbach's $\alpha > 0.7$ (Naveiro-Rilo et al., 2010).

The *European Heart Failure Self-Care Behavior Scale* ((EHFScB), a 9-item selfadministered questionnaire was used to measure the pre and post intervention self-care behavior (Appendix G). A 5-point Likert scale is used and the score range is from 9 to 45, with the lower number pointing towards better self-care (Lee et al., 2013). Permission to use this questionnaire was obtained from the author. The reliability for the nine-item scale was acceptable (0.80) and Cronbach's alpha ranged from 0.68 and 0.87 across different countries (Jaarsma, Arestedt, Martensson, Dracup & Stromberg, 2009).

Patient satisfaction was measured by offering a satisfaction survey rated on a five-point Likert scale (Appendix H). This survey was developed by the co-investigator; validity was established by two experts who are nurse practitioners with experience in primary care and managing patients pre and post hospital discharge.

Data Collection and Analysis

Post intervention QOL, SCB and satisfaction surveys were collected after the 12th week home visit. Hospital readmission data was collected through tracking hospital admission data from the health records and patient reports. All data analyses were performed using Statistical Package for the Social Sciences (SPSS) version 23 with a statistical significance level set at \leq .05. Friedman test was performed since there were more than two measurements/outcome variables (QOL, SCB and satisfaction) from same participants.

Budget

Total costs for the project were estimated to be \$14,526.00 (Appendix I). In-kind support in the amount of \$10,558.00 was provided by the project site. A \$4,000 grant to cover the balance of the cost was awarded by the American Association of Colleges of Nursing and the Centers for Disease Control and Prevention (AACN/CDC) with support of the Academic Partners to Improve Health (APIH) (Appendix J).

Results

Demographic Data

Twelve patients were eligible for the project; three refused the home visits and two were not Medicare/Medicare Advantage beneficiaries. The average age of the remaining patients (n = 7) was 79 (SD = 6.74) years and the ages ranged from 70 to 90 years of age. Most of the participants were females (71%, n = 5) and males were 29% (n = 2). All participants were Caucasian and retired (100%, n = 7); 57% were married and 43% were either single or widowed. Seventy-two percent of the participants had either college or doctoral degree as education. The cardiologist was mainly managing the heart failure for most of the participants (86%) and all the participants had an average of two chronic conditions (SD = .577). The average number of prescription medications was 11 (SD = 1.38) and all the participants scored well for social support. All of the participants had either an emergency room visit (SD = 1.55) or a hospitalization (SD = 1.11) in the past six months (Appendix K, Table 2).

Outcomes

Readmissions. There were no readmissions at 30 days post discharge (SD=.00). There was one readmission after 30 days and one direct admit after 30 days (SD=.38) (Table 3).

Quality of life. The average score for pre-intervention QOL was 49 (SD=13.29) with the median score of 51 and the total score ranged from 32-72. Post-intervention, the average score dropped to 30 (SD=10.19), median score to 27 and the total score ranged from 18-43. The lesser number indicates improved QOL post intervention (Table 4). **Self-care behavior.** The mean score for pre-intervention SCB was 25 (SD=5.56) with a median score of 24 and the total score ranged from 17-34. A lesser score signifies better self-care. After intervention, a significant improvement was noticed in the self-care behaviors with a median and mean score of 14 (SD=2.14) and a total score ranged from 12 to 17 (Table 5).

Satisfaction. All the patients were satisfied with the TCP except for pharmacy service. Only one patient used the home based pharmacy and was not satisfied with the service. Due to variation in BP, frequent changes were made in this patient's medication regimen that contributed to the dissatisfaction. The mean satisfaction score was 24 (SD = .38) with a median score of 24 and the total score ranged from 23 to 24 (Table 6).

A Friedman test demonstrated a positive effect from the interventions on patient's QOL, self-care management and satisfaction ($\chi^2 = 30.35$, p = .000) (Table 7). The average

QOL and SCB mean score is significantly reduced which indicates better quality of care and better self-management. The intervention had a large effect on the outcome variables resulting in an increase in QOL and SCB scores post-intervention (Effect Size = -1.4 and -2 respectively).

Discussion

As evidenced by research, TCP conducted in the family practice clinic had a significant effect on reducing readmissions and resulted in improved patient outcomes. This TCP was well organized and helped the patients to increase their awareness and utilization of the transitional care interventions. Patients were also educated on resources that are available for an emergency in their PCP's office like 24-hour triage line and an on-call physician services. TCP encouraged the patients to use the urgent care instead of emergency room (ER) to reduce health care cost. Developing and maintaining a relationship with the older population is very difficult. Once the providers developed a rapport and gained the patients' trust, the participants were more cooperative and followed the instructions. The home delivery pharmacy within the transitional care program was underutilized because most of the participants were enrolled in a mail order pharmacy service.

Limitations and Implications

Small participant numbers was one of the limitations of this project and it was due to limitations of the selection criteria and lack of patient-interest. The project focused on HF patients and was designed for only Medicare beneficiaries due to limited data availability at the ACO regarding the hospitalizations and ER visits for patients with other types of insurance. The pool of patients could have been larger if more types of chronic conditions and insurance coverage were included as eligible for the project. Reimbursement was another challenge encountered throughout the program. Medicare will pay the provider for transitional care services once in 30 days per patient following a discharge. Home visit billing codes could not be used for a family practice clinic since the practice is not credentialed to do home care. Although, research indicates the benefit of weekly home visits for the first few weeks, it is not in practice due to billing limitations. Some patients did not require 12 home visits; therefore the project could have been designed for a minimum of 1-2 home visits and as needed for 12 weeks.

For hospital follow up visit in the office, the providers only get an average of 15 minutes to see the patient which is not sufficient for the clinicians to go through the health records and discharge instructions; perform medication reconciliation, patient education and history of physical illness for the current visit. Patients need supportive resources and more education to promote daily functioning and self-care activities that helps with the transition. Hence it is recommended to have a TCP in solo private practices to improve patient outcomes and communication.

Doctoral projects can be embedded in local communities through partnerships with growing ACOs to improve the quality of care in the community as well as to promote sustainable changes in the organization and population. Timely and effective TCIs can reduce readmissions of HF patients within 30 days of hospital admission and increase QOL, SCB and satisfaction. TCPs are not revenue generating at outset due to reimbursement issues, however future considerations of a multidisciplinary team approach with convenient workflow may be explored for the financial benefits to support sustainability. The interdisciplinary team can be cost and quality effective; the cost saving becomes the source of revenue to support the program. Financial savings associated with the MSSP, high quality service and reduced health care costs would be some of the benefits to the ACO in the future. As soon as a suitable workflow with multidisciplinary team is developed, TCP can be promoted and replicated in other practices within this ACO.

Conclusion

The large gaps in care during transition from one setting to another can lead to unmet needs, poor satisfaction with care and increased readmission rates. Avoidable rehospitalizations are a costly burden for payers as well as for acute care hospitals. An APRN led TCP was developed and implemented as part of an existing primary care practice setting to improve the hospitalizations and readmission rates. Through this project, it is suggested that successful TCPs might be conducted in any settings including private practices. TCPs facilitate improved communication between the hospital and primary care providers as well as with the patients, which in turn improves the patient outcomes and reduces length of hospital stay, morbidity and mortality rates and healthcare cost.

The quality of services rendered to the patients could be improved through better coordination and enhanced communication. Patients may become more cooperative and compliant with the treatment plan, which in turn may increase the patient's functional status, QOL and SCB. In conclusion, based on the results, the TCP was successful in reducing hospital readmissions and increasing patients' QOL, self-care management and satisfaction. Either payment reform or innovative billing strategies may be required for sustainability of the TCPs or a future effort will be crucial to develop a workflow with a multidisciplinary team approach to achieve cost effectiveness.

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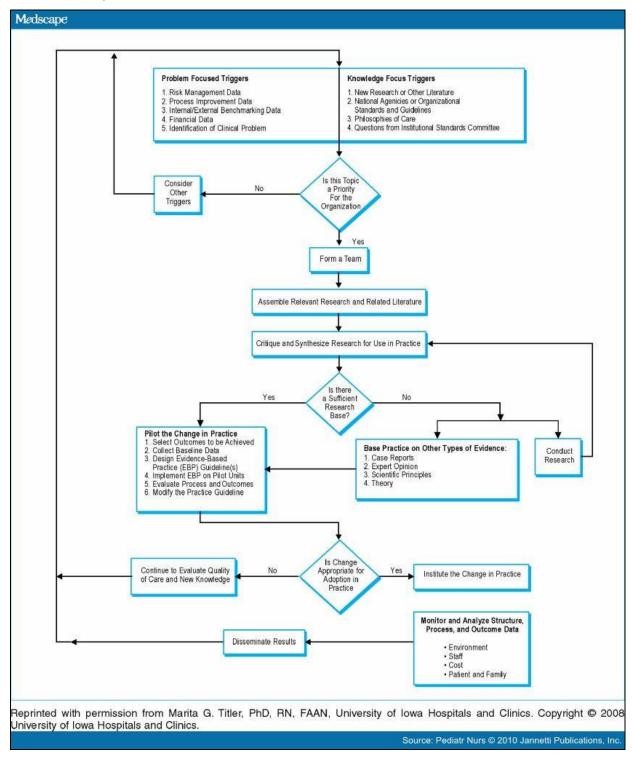
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Appendix A

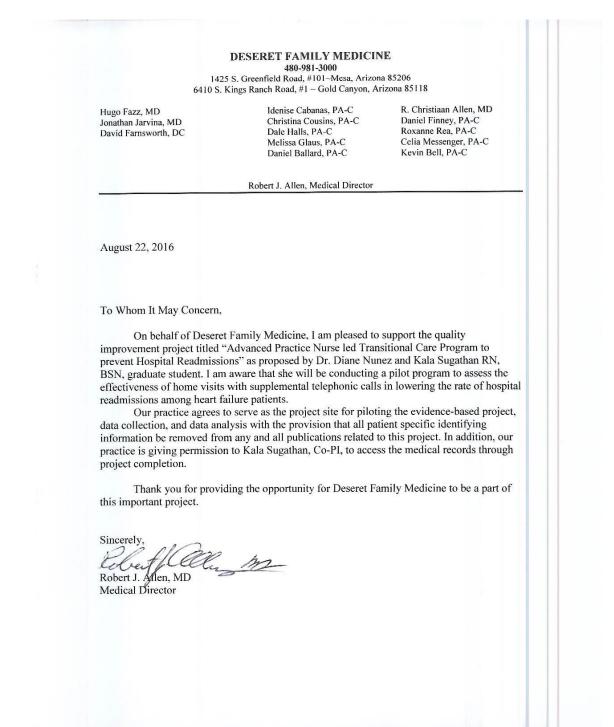
IOWA model of EBP



The Iowa Model of Evidence-Based Practice to Promote Quality Care (Titler et al., 2001)

Appendix B

Clinical Site Authorization letter



Appendix C

IRB Approval letter



APPROVAL: EXPEDITED REVIEW

Diane Nunez CONHI - DNP 602/496-0751 DIANE.NUNEZ@asu.edu

Dear Diane Nunez:

On 8/19/2016 the ASU IRB reviewed the following protocol:

T (D)	
Type of Review:	Initial Study
Title:	Advanced Practice Nurse led Transitional Care Program to Prevent
	Hospital Readmissions
Investigator:	Diane Nunez
IRB ID:	STUDY00004742
Category of review:	(4) Noninvasive procedures, (7)(a) Behavioral research
Funding:	Name: American Association of Colleges of Nursing
Grant Title:	
Grant ID:	
Documents Reviewed:	• Sugathan_ACO_ transitional care_Authorization letter.pdf, Category: Off-site authorizations (school permission, other IRB approvals, Tribal permission etc);
	 Sugathan- Permission for using European Heart Failure Self-Care Behavior Scale.pdf, Category: Other (to reflect anything not captured
	above);
	• Sugathan_Consent for Organizational Readiness Survey.pdf, Category: Participant materials (specific directions for them);
	• Nunez_2014_citiCompletionReport2224391.pdf, Category: Vitaes/resumes of study team;
	Sugathan EBP proposal.pdf, Category: Sponsor Attachment;
	Sugathan_Blood pressure & Wt log.pdf, Category: Participant
	materials (specific directions for them);
	 Sugathan_K_CITI Training2016.pdf, Category: Vitaes/resumes of study team;
	• Sugathan_TCP_Demographic Questionnaire.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions);
	• Sugathan_TCP_Education on Exercise.pdf, Category: Participant materials (specific directions for them);
	Sugathan_PATIENT SATISFACTION SURVEY.pdf, Category:
	Measures (Survey questions/Interview questions /interview guides/focus group questions);
	• Sugathan_measurement tool_EHFScB-9.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions);
	 Sugathan_Consent for Organizational Readiness Survey.pdf, Category: Consent Form;
	• Sugathan_HIPPA form for patients.pdf, Category: Off-site authorizations (school permission, other IRB approvals, Tribal
	 permission etc); • Sugathan_Diet and Congestive Heart Failure.pdf, Category: Participant materials (specific directions for them);

 Sugathan_Cover letter.pdf, Category: Consent Form; Sugathan_ esorganizationalreadinesssurvey.pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); Sugathan_Minnesota Living with Heart Failure Questionnaire permission.pdf, Category: Other (to reflect anything not captured above); Sugathan_2016permission ASU_Organizational readiness.pdf, Category: Other (to reflect anything not captured above); Sugathan_Cover letter.pdf, Category: Recruitment Materials; Sugathan_Cover letter.pdf, Category: Other (to reflect anything not captured above); Sugathan_Master list.pdf, Category: Other (to reflect anything not captured above); Sugathan_Education_Exercise Tips.pdf, Category: Participant materials (specific directions for them); Sugathan_Cover letter.pdf, Category: Participant materials (specific directions for them); Kugathan_IRB Applicatin_Final.docx, Category: IRB Protocol; Sugathan_measurement_MLHFQ_questionnaire_1pdf, Category: Measures (Survey questions/Interview questions /interview guides/focus group questions); Sugathan_Education_How Can I Keep My Heart Failure From Worsening.pdf, Category: Participant materials (specific directions for them); Sugathan_Student Privacy & Confidentiality Agreement.pdf, Category: Off.
 Measures (Survey questions/Interview questions /interview guides/focus group questions); Sugathan_Education_How Can I Keep My Heart Failure From Worsening.pdf, Category: Participant materials (specific directions for
 Sugathan_Student Privacy & Confidentiality Agreement.pdf, Category: Off-site authorizations (school permission, other IRB approvals, Tribal permission etc); Sugathan_Grant approval letter.pdf, Category: Sponsor Attachment; Sugathan_Recruitment_Flyer.pdf, Category: Recruitment Materials; Sugathan_HIPPA policies and procedures for the practice.pdf,
Category: Other (to reflect anything not captured above); • Sugathan_Projected Costs.pdf, Category: Resource list;

The IRB approved the protocol from 8/19/2016 to 8/18/2017 inclusive. Three weeks before 8/18/2017 you are to submit a completed Continuing Review application and required attachments to request continuing approval or closure.

If continuing review approval is not granted before the expiration date of 8/18/2017 approval of this protocol expires on that date. When consent is appropriate, you must use final, watermarked versions available under the "Documents" tab in ERA-IRB.

In conducting this protocol you are required to follow the requirements listed in the INVESTIGATOR MANUAL (HRP-103).

Sincerely,

IRB Administrator

cc: Kala Sugathan Kala Sugathan

Appendix D

Cover letter and consent

Advanced Practice Nurse led Transitional Care Program to Prevent Hospital Readmissions

Dear Participant,

I am a graduate student under the direction of Professor Dr. Diane Nunez DNP, RN, ANP-BC, FNAP in the College of Nursing and Health Innovation at Arizona State University. I am conducting an evidence based pilot program to see if an advanced practice nurse led transitional care program will reduce or prevent readmissions and improve patient quality of life and satisfaction.

I am inviting you to participate in the pilot program because you were identified as a potential participant by your primary care physician due to the risk of being readmitted into the hospital. This project includes home visits with supplemental telephonic calls for 12 weeks. Physical assessment, medication reconciliation, and education on medications, self-care behaviors and symptom management will be performed during the visit. Initial data collected will include demographic questionnaire. The home visit will be approximately 30 minutes and will be conducted once a week for 12 weeks. The telephonic call which may take 2-3 minutes will be made once a week for 12 weeks to check on patients, maintain a good relationship, build trust and assure the continuity of care. Post intervention survey will be completed to determine the impact of the project on quality of life, self-care behavior and satisfaction. You have the right not to answer any questions, and to stop participation at any time during the program.

Brisma Pharmacy does home delivery at no additional cost and accept all major insurance including Medicare, Medicaid (AHCCCS) plans and Magellan. Researchers and project personnel have no affiliation or relationship with this pharmacy. It is selected only for its geographic location to project site and potential participants. Participants having difficulty in picking up medications from the pharmacy can change the pharmacy to Brisma pharmacy. Changing pharmacy is not mandatory.

Your participation in this pilot program is voluntary. If you choose not to participate or to withdraw from the program at any time, there will be no penalty. It will not affect the care you receive prior to, during, or after your participation in the program. Participation in this project will not affect your treatment in the primary care clinic. You must be 50 years of age or older to participate in this program. There is no known risk greater than those that are associated with everyday types of activity.

Your responses on the questionnaires will be confidential and will be identified only by a number. The results of this study may be used in reports, presentations, or publications, but the assigned ID number will not be connected to your name or other personal identifying information. The ID number will be connected to names through a master list and the names will not appear directly on any participant data forms and will be linked only with a list matching your name and ID number in a form that will be kept confidential by the co-investigator.

The graduate student will have access to your health records from the clinic in order to document the care and services rendered by the transitional care program into the electronic medical records. Agreeing to participate in this program will be considered as your consent for the student to access the medical records. If you have any questions concerning this program, please contact the following team members:

Kala Sugathan BSN, RN, DNP student at 480-826-3427 Dr. Diane Nunez, DNP, RN, ANP-BC, FNAP at 602-496-0751

If you have any questions about your rights as a participant in this project, or if you feel you have been placed at risk, you can contact the Chair of the Human Subjects Institutional Review Board, through the ASU Office of Research Integrity and Assurance, at (480) 965-6788.

Sincerely, Kala Sugathan BSN, RN, DNP student Dr. Diane Nuñez DNP, RN, ANP-BC, FNAP

By signing below you are agreeing to be part of the project. Name:

Signature:

Date:

Appendix E

Demographic Questionnaire

ID _____

Date _____

Transitional Care Project Demographic Questionnaire

Please check the box that best	corresponds to	your answer	[.] or provide	a response	for each
	question	below		-	

1. Age
2. Gender - Male Female
3. Race/Ethnicity -
African American
Asian
Hispanic or Latino
Native Hawaiian or other Pacific Islander
Other (please specify):
4. Marital Status –
Married
Divorced
Widow/Widower
Living with partner
6. Employment Status
Employed
Unemployed
Retired
7. Highest Level of education:
Less than High School graduate
High school graduate
Technical School
Some College
College degree
Masters degree
Doctoral degree
Post graduate degree

8. Chronic conditions:
Diabetes Mellitus
Kidney disease
Arthritis
Asthma
High blood pressure
Other (please specify):
9. Who is managing your heart failure?
Cardiologist
Primary care/Internal Medicine
□ None
10. How many <i>prescription</i> medications are you taking currently?
11. Do you feel you have Social support (Family member/care giver), if so whom?
No Yes
12. What is your current housing?
House
Rent
Apartment
Group home
Homeless
13. Last hospitalization
14. Last Emergency Department visit
15. How many times did you go to the Emergency during the past 6 months?
16. How many times did you stay in a hospital during the past 6 months?

Appendix F

Instrument: Measure quality of life

MINNESOTA LIVING WITH HEART FAILURE® QUESTIONNAIRE

The following questions ask how much your heart failure (heart condition) affected your life during the past month (4 weeks). After each question, circle the 0, 1, 2, 3, 4 or 5 to show how much your life was affected. If a question does not apply to you, circle the 0 after that question.

Did your heart failure prevent you from living as you wanted during the past month (4 weeks) by -	No	Very Little			Ver	y Much
 causing swelling in your ankles or legs? making you sit or lie down to rest during 	0	1	2	3	4	5
the day?	0	1	2	3	4	5
making your walking about or climbing stairs difficult?	0	1	2	3	4	5
making your working around the house or yard difficult?	0	1	2	3	4	5
making your going places away from home difficult?	0	1	2	3	4	5
6. making your sleeping well at night difficult?	0	1	2	3	4	5
 making your relating to or doing things with your friends or family difficult? 	0	1	2	3	4	5
 8. making your working to earn a living difficult? 	0	1	2	3	4	5
9. making your recreational pastimes, sports	-	-				
or hobbies difficult?	0	1	2	3	4	5
 making your sexual activities difficult? making you eat less of the foods you 	0	1	2	3	4	5
like?	0	1	2	3	4	5
 making you short of breath? making you tired, fatigued, or low on 	0	1	2	3	4	5
energy?	0	1	2	3	4	5
14. making you stay in a hospital?	0	1	2	3	4	5
15. costing you money for medical care?	0	1	2	3	4	5
16. giving you side effects from treatments?	0	1	2	3	4	5
17. making you feel you are a burden to your family or friends?	0	1	2	3	4	5
18. making you feel a loss of self-control						
in your life?	0	1	2 2	3 3	4	5
 making you worry? making it difficult for you to concentrate 	0	1			4	5
or remember things?	0	1	2	3	4	5
21. making you feel depressed?	0	1	2	3	4	5

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Appendix G

Instrument: Measure self-care behavior

The European Heart Failure Self-Care Behavior Scale_9

This scale contains statements about heart failure self-care. Respond to each statement by circling the number you think best applies to you. Note that the different answer alternatives constitute a scale ranging between the extremes of "I completely agree" (1) to "I don't agree at all" (5). Even if you feel uncertain about a particular statement, circle the number you feel is most true for you.

	I completely agree				I don't agree at all
1. I weigh myself every day	1	2	3	4	5
 If my shortness of breath increases I contact my doctor or nurse. 	1	2	3	4	5
3. If my feet/legs become more swollen than usual I contact my doctor or nurse.	1	2	3	4	5
4. If I gain 4.5 lbs in one week I contact my doctor or nurse.	1	2	3	4	5
5. I limit the amount of fluids I drink (not more than 1 ¹ / ₂ -2 1/day: 6 to 8 cups)	1	2	3	4	5
6. If I experience increased fatigue I contact my doctor or nurse	1	2	3	4	5
7. I eat a low salt diet	1	2	3	4	5
8. I take my medication as prescribed	1	2	3	4	5
9. I exercise regularly	1	2	3	4	5

The European Heart Failure Self-care Behavior Scale (Jaarsma, Stromberg, Martensson, Dracup, 1999) Appendix H

Instrument: Patient Satisfaction Survey

ID _____

Date _____

PATIENT SATISFACTION SURVEY

Please read the following statements carefully and *circle* one number on each line which indicates how strongly you agree or disagree.

		Strongly Disagree	Disagree	Agree	Strongly Agree
1	The TCP team provided adequate information about the disease condition and management.	1	2	3	4
2	The instructions were easy to follow.	1	2	3	4
3	I felt that I had enough resources to manage my health condition.	1	2	3	4
4	I would rate the quality of services provided by the advanced practice providers as excellent.	1	2	3	4
5	I am extremely satisfied on home delivery of medications.	1	2	3	4
6	Overall, I am satisfied with the TCP providers and services	1	2	3	4
7	I will recommend this program to a friend or a family member.	1	2	3	4
8	What did you like most about the TCP?	1	1	L	1
9	What aspects of the program could be imp	proved?			

Appendix I

Table 1

Projected cost

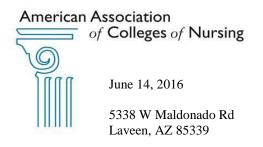
Expense Item	Expenses	In-Kind Support
Personnel	*	**
Project director (DNP student)	\$2184.00 (35%)	\$4056.00 (65%)
\$40/hr for ~13 hrs per week X		
12 weeks		
Supervising Physician @75/hr		\$900.00
1hour/week for 12 weeks		
Office staff/MA for		\$28.00
readmission tracking, \$14/hr x		
2hrs		
Advanced practice provider @		\$4128.00
\$43/hr (8hrs/week for 12		
weeks)		\$11<00
Pharmacist @ \$58/hr x 2 hrs		\$116.00
Equipment/Materials	¢105.00	
Tools for patient assessment	\$195.00	
Thermometer \$30.00		
BP cuff \$30.00		
Bag \$30.00 Stethoscope \$ 80.00		
Pulse oximeter \$25.00		
Cell phone to call patients for		\$300.00
12 weeks		4500.00
Laptop for the project use		\$600.00
(documenting the home visit for		\$000100
12 weeks)		
Patient paper charts	\$75.00	
Copying patient's EMR for	\$50.00	
paper chart		
Pill cutter for each patient	\$60.00	
@\$5.00 X 12		
Pill organizer @ \$6.00 X 12	\$72.00	
pts		
BP machine @\$30.00 for 12 pts	\$360.00	
Digital weighing scale	\$300.00	
@\$25.00 X 12 pts		
Education materials	\$72.00	
\$6/pt X 12 pts		
Pulse oximeter \$25 X 12pts	\$300.00	

Gift cards for 12 patients	\$300.00		
(\$25.00 each)			
Magnetic business cards (12)		\$30.00	
Office/Operations			
Utilizing physician's office and		\$200.00	
computer for checking the			
EMR to identify patients 4			
hours/week for 3 weeks			
Utilizing physician's office and		\$200.00	
computer for outcome data			
collection			
Total Expenses	\$3968.00	\$10558.00	

A funding of \$4,000 has been granted for this project from American Association of Colleges of Nursing and the Centers for Disease Control and Prevention (AACN/CDC) with support of the Academic Partners to Improve Health (APIH).

Appendix J

Grant letter



Dear Ms. Kala Sugathan:

We are pleased to inform you that your DNP Evidence-Based Population Health Project has been recommended for funding by our expert advisory. The decision to award you this funding of \$4,000 was made after a careful review of your application materials.

Your proposal was awarded high scores. Congratulations on an excellent proposal!

To begin, we would like to publicize your award on our AACN Website and communications materials. If you have any objections, please notify Ms. Allison Jacobs.

We ask you acknowledge the support of the Academic Partners to Improve Health (APIH) in any publications. We can provide you with approved acknowledgement wording when needed.

Please note due to federal restrictions funding can **only** be dispersed in four equal quarterly payments **after** receipt and acceptance of the required progress reports. Due dates for the quarterly reports are listed below and a template for the reporting is attached to this email.

Quarterly Report/Funds Disbursement Dates: September 15, 2016

December 15, 2016 (Note: The second quarterly payment will be contingent on IRB

approval or documentation of exemption for the project.) March 15, 2017

June 17, 2017 (Final Report Due)

To advise us of your intentions, please email Ms. Allison Jacobs, CDC Project Manager, directly indicating your acceptance or declination of this offer. Her email is <u>ajacobs@aacn.nche.edu</u>. In addition, she will be your AACN point of contact during the project period. If you have additional questions, please do not hesitate to contact her.

Thank you for your continued efforts in population health. Sincerely,

Joan M. Stanley

Joan Stanley, PhD, CRNP, FAAN Senior Director of Education PolicyAmerican Association of Colleges of Nursing

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Appendix K

Statistical Analysis

Table 2

Demographics

	Percent	Frequencies	Mean (SD)
	(%)		
Age			79.14 (6.74)
Gender:			
Female	71.4	5	
Male	28.6	2	
Race/Ethnicity:			
African American	0	0	
Asian	0	0	
Caucasian	100	7	
Hispanic or Latino	0	0	
Native Hawaiian or Pacific	0	0	
Islander			
Other	0	0	
Marital Status:			
Married	57.1	4	
Single	14.3	1	
Divorced	0	0	
Widow/widower	28.6	2	
Living with partner	0	0	
Employment status:			
Employed	0	0	
Unemployed	0	0	
Retired	100	7	
Highest level of education:			
Less than high school	0	0	
High school graduate	28.6	2	
Technical school	0	0	
Some College	28.6	2	
College degree	28.6	2	
Masters degree	0	0	
Doctoral degree	14.3	1	
Post graduate degree	0	0	
Chronic conditions:			2.00 (.58)
Heart Failure management:			× /
Cardiologist	85.7	6	
Primary care/Internal medicine	14.3	1	
None	0	0	

Prescription medications:			10.71 (1.38)
Social support:			
No	0	0	
Yes	100	7	
Current Housing:			
House	71.4	5	
Rent	0	0	
Apartment	28.6	2	
Group home	0	0	
Homeless	0	0	
Number of ER visits in the past six	<u>í</u>		
months:			1.00 (1.55)
Number of hospitalizations in the			
past six months:			.71(1.11)

Table 3

Readmission data

	Ν	Mean score (SD)
Readmission at 30 days	7	.00 (.00)
Readmission after 30 days	7	.14 (.38)
Direct admit	7	.14 (.38)

Table 4

Pre and Post intervention QOL Score Results

	Ν	Mean score (SD)	Median score	Range
Pre-Intervention	7	49.29 (13.29)	51	32-72
Post-Intervention	7	29.71 (10.19)	27	18-43

Table 5

Pre and Post intervention SCB Score Results

	Ν	Mean score (SD)	Median score	Range
Pre-Intervention	7	25.43 (5.56)	24	17-34
Post-Intervention	7	14.29 (2.14)	14	12-17

Table 6

Satisfaction results

	Ν	Mean score (SD)	Median score	Range
Satisfaction score	7	23.86 (.38)	24	23-24

Table 7

Friedman Test

	Test statistics
N	7
Chi-Square	30.35
df	5
Significance	.000

Effect size (ES)

 $ES = Mean (posttest group) - Mean (pretest group) \div SD (pretest group)$

ES for MLHFQ = 29.71 – 49.29/ 13.29 = -1.4

ES for SCB = 14.29 - 25.43/5.56 = -2