

Transitional Care Intervention to Reduce 30-day Readmission Rate in  
Cardiac Transplant Patients

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Approved May 2016 by the faculty of UMKC in partial fulfillment of the requirements for the  
degree of Doctor of Nursing Practice

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## Abstract

Readmission remains a financial burden in our healthcare arena. Billions of dollars in hospital payments were made from Medicare towards readmissions. The problem of patients' ineffective transitions during hospital discharge leads to an increased readmission rate. The purpose of the pilot study was to examine the effectiveness of the transitional care interventions during post hospitalization in reducing 30-day readmission rate in cardiac transplant patients. The quasi-experimental study used a retrospective group (baseline, usual discharge care) and a prospective group who received the transitional care interventions. The study was implemented in an outpatient medical center in New York City. The convenience consecutive sampling size was 43 participants. The transitional care interventions consisted of four components conducted by the advanced practice registered nurse: (1) meeting with the participants at the hospital, (2) facsimiles of discharge summaries, (3) scheduling a follow-up appointments, and (4) telephone call follow-up for 30 days post hospital discharge. The intervention group had a 30-day readmission rate of 8.3% (2/24) compared to 36.8% (7/19) in the usual group. The results indicated a significant decrease in the 30-day readmission rate among cardiac transplant patients who received the transitional care interventions ( $p=0.03$ ). In the intervention group, transitional care provided the cardiac transplant patients with smooth, safe, and efficient transitions from hospital to home which can reduce the 30-day readmission rate. The transitional care intervention program can improve safety and quality of care in the healthcare system.

*Keywords:* transitional care, readmission, heart transplant, transitional care intervention

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The Centers for Medicare and Medicaid Services (CMS, 2014) reported that one in five patients discharged from hospitals are readmitted within 30 days across the United States (U.S). In 2004, an estimated \$17 billion in hospital payments were made from Medicare towards readmission (Jencks, Williams, & Coleman, 2009). As a result, in October 2013, the Affordable Care Act mandated the federal government to establish a Hospital Readmission Reduction Program (HRRP) to reduce cost in health care systems (CMS, 2014). Consequently, as of 2015, the program penalized as high as 3% to hospitals with excessive readmission which is defined as admission within 30 days of discharge (CMS, 2014). The impact of readmissions can threaten to overwhelm an already economically exhausted U.S. health care delivery system (Agency for Healthcare Research and Quality, 2013). According to data from 2008, nearly 15% of all initial hospital stays in New York State resulted in a readmission within 30 days and cost the state a substantial \$3.7 billion per year (New York State Health Foundation, 2011).

The CMS noted higher readmission rates in hospitals with vulnerable populations. In cardiac transplantation, readmission is common related to high risk of infection and rejection (Organ Procurement and Transplantation Network [OPTN] and Scientific Registry of Transplant Recipient [SRTR], 2014). Cardiac transplantation is the treatment of choice for symptomatic patients with end-stage heart failure who are not responsive to medical treatment (Mancini & Lietz, 2010). In patients with cardiac transplant, about 36% will be hospitalized during the first year and 61% in the fourth year (OPTN & SRTR, 2014).

Studies found that 15% to 45% of patients with medical-surgical illnesses that were readmitted did not know their medications and did not have follow up care with their primary

care provider (Peikes, Lester, Gilman, & Brown, 2013). Also, Jencks et al. (2009) reported that 69% of the patients with medical diagnosis and 53% with a surgical diagnosis were either readmitted or died within one year after their initial hospitalizations. The evidence shows that there is a problem during transition, communication, and coordination between hospital providers and healthcare professionals providing care after the patient is discharged (Arbaje et al., 2010; Peikes et al., 2013; Shugarman & Whitenhill, 2011). Therefore, implementation of a transitional care intervention (TCI) has been identified as one means of reducing readmission rate (Stauffer et al., 2011; Naylor et al., 2004). The TCI aligned with the HRRP program and the Institutes of Medicine proposed six aims for improvement.

In the 31<sup>st</sup> registry data, Lund et al. (2014) reported that there were 104,027 adult heart transplants worldwide as of June 30, 2013. Although members of the ethnic minority group continue to increase, the 2012 report shows that 67% of the heart transplants were white, 20% black, 9% Hispanic, and 4% Asian (OPTN & SRTR, 2014). This current study on TCI implementation was conducted in an outpatient medical center in New York City. In 2010, the United States Census Bureau (2015) reported that 44% living in New York City were white, 26% black, 29% Hispanic, and 13% Asian.

### **Problem, Purpose**

#### **Problem Statement**

In cardiac transplant, the problem of patient's ineffective transition during hospital discharge can lead to an increase in readmission rate. Patients who are readmitted do not know their medications and lack of follow up care with their primary care provider (PCP) or transplant cardiologist (Peikes et al., 2013). There is a miscommunication problem between providers and patients during post hospital discharge, and evidence shows that lack of coordination during

transitions can result in an increased readmission (Arbaje et al., 2010). Ineffective transition can cause problems in quality and safety during post hospital discharge.

### **Purpose**

The purpose of the quasi-experimental pilot study was to examine the effectiveness of transitional care interventions during post hospitalization on reducing 30-day readmission rate in cardiac transplant patients.

### **Facilitators and Barriers**

The major facilitators and contributors to the study were the medical director, administrator, cardiologists, cardiac transplant patients, and patients' caregivers. The barriers and challenges included missing patient information from the medical records, overwhelming patient load by the advance practice registered nurse (APRN) who conducted the TCI, the cardiologist and nurse's lack of time and knowledge of the intervention, and patient's difficulty with maintaining the intervention due to socioeconomic status. The study cost \$32,000 for three months (see Appendix D), and no funds were received for this study. After the study was completed, the cardiac transplant department retained the TCI tools to reduce readmission for the heart transplant patients. The positive results of the pilot study supported the investigator's pursuit for grant funding to continue the project for one year.

### **Review of the Evidence**

#### **PICOT**

The PICOT question was, "In cardiac transplant patients, will the implementation of the transitional care intervention after discharge compared to routine hospital discharge demonstrate a decrease in readmission rate during a 30 day period?"

#### **Literature Search Strategies**

A review of the literature was undertaken to identify the evidence regarding readmission rates in the cardiac transplant population or the chronic illness population and the effect of a transitional care intervention. The search strategy aimed to find both published and unpublished studies in human research and English language from January 2009 through March 2015. The following databases were utilized in the search of evidence: Cochrane, PubMed, CINAHL, Ovid Medline, and Joanna Briggs Institute EBP. Multiple key word combinations were used: transitional care, readmission, heart transplant, transitional care intervention, transitional care model, care coordination, discharge planning, discharge process, rehospitalization, cardiac transplant, and heart failure. Google Scholar was accessed to search for national guidelines related to discharge planning and transitional care. Although the plan was to include only high level evidence in the last six years, one study was included from 2004 that is a multisite randomized controlled study.

After considering the inclusion and exclusion criteria and evaluating the level of evidence for each study, the search yielded 21 studies. The 21 studies included five systematic reviews with meta-analysis, one systematic review, one integrative literature review, three randomized control trials (RCT), two quasi-experimental, one prospective non-randomized, three cohorts, two descriptive, and three national guidelines (see Appendix A). Based on a hierarchy of evidence rating system (Melnyk & Fineout-Overholt, 2011), ten studies were level I, three were level II, three were level III, three were level IV, and two studies were level V1.

### **Synthesis of Evidence**

Although the primary objective of the synthesis review was to show the effect of the transitional care intervention in hospital readmission rates, the review also noted the effect of the TCI in nurse-led interventions, cost effectiveness, quality of life, and satisfaction. The single

TCIs were effective but most of the studies in the synthesis found that bundled TCI significantly reduced readmission rate.

### **Bundled Transitional Care Intervention**

TCI prevents readmissions and poor outcomes from uncoordinated care (Feltner et al., 2014). Interventions with multiple components were more effective than single interventions in medical and surgical patients (Leppin et al., 2014). In the synthesis review, several strategies of transitional care intervention were stated and included telephone call follow-ups, follow-up appointments, nurse-led coordination, medication reconciliations, facsimiles of patients' discharge summaries, multidisciplinary clinics, in-patient education, engagement of patients and caregivers, and home care.

In systematic reviews by Feltner et al. (2014), Verhaegh et al. (2014), and Slyer, Concert, Eusebio, Rogers, and Singleton (2011), bundled TCI had a positive effect on readmission. Feltner et al. reported that home visit, structured telephone support (STS), and a moderate to high multidisciplinary heart failure (MDS-HF) clinic were effective in reducing three to six months all cause readmission. The study by Verhaegh et al. revealed that home visit, care coordination, and communication between the hospital and the PCP can reduce short-term readmission rates in patients who are 60 years and older with chronic illness. Also, Slyer et al. endorsed that interventions utilizing home visits, or home visits coupled with telephone follow-up, showed a more favorable reduction in readmission rates of HF patients. Furthermore, an integrative review by Stamp, Machado, and Allen (2014) indicated that home visits alone or in combination with telephone calls were the most successful interventions in decreasing readmission in patients 18 years and older with heart failure.



Randomized controlled trials by Wong, Chow, Chan, and Tam (2014); Saleh, Freire, Morris-Dickinson, and Shannon (2012); and Naylor et al. (2004) also concluded that bundled TCI had positive effects on reduction in readmission rates. After one and three months, Wong et al. found that home visit (10.7%, 21.4% respectively) and telephone follow up (11.8%, 20.6% respectively) had decreased readmission rates in medical patients compared to the control group (17.6%, 25.7% control). Naylor et al. noted that HF patients receiving TCI had a lower readmission rate ( $p=.047$ ) within 52 weeks. The TCI included APRN-led discharge planning, follow-up visit with the PCP, telephone follow-up, and home visit. The interventions in Saleh et al. study included a patient-centered health record, a structured discharge checklist, coordination of data flow, and follow up appointments. During three to 12 months after discharge, Saleh et al. findings revealed that Medicare beneficiary patients had fewer readmissions in the TCI group than the control group (48.2% versus 58.2%).

In a prospective, non-randomized controlled trial, two-center pilot study, Huntington, Guzman, Roemen, Fieldsend, and Saloum (2013) revealed that the overall 30-day all-cause readmission rate was reduced by 42% in HF patients ( $p=.043$ ) who received TCI. The TCI included home visit, medication reconciliation, timely follow up, and an educational intervention. In a quasi-experimental pre-post study by Dedhia et al., an intervention consisting of follow up appointment, discharge summary fax to the PCP, and medication reconciliation found that the intervention group had a lower 30-day readmission rate (22% vs 14%). Even after three months of study, a prospective, quasi-experimental study by Naylor et al. (2013) revealed that transitional care models (TCM) reduced the number of readmissions (45 vs. 60,  $p < 0.041$ ) in 65 years and older patients with chronic illness. The intervention included nurse-led TCM, evidenced-based plan of care, home visits, telephone follow up, and follow up with PCP.

Similarly, in a prospective study of Stauffer et al. (2011), the interventions were three-month APN-led intervention, home visits, and follow up by telephone calls. In the study, the adjusted 30-day readmission rate was 48% lower in post intervention than pre intervention in patients with HF. Also a study by Jackson, Trygstad, DeWalt, and DuBard (2013) noted that the participants from the transitional care had 20% lower adjusted readmission rates compared to usual care. In a retrospective cohort study, comprehensive medication management, face-to-face education for patients and families, and follow up with the PCP were effective in prevention of one readmission for every six patients with chronic illness. In a cross sectional study by Bradley et al. (2013), medication reconciliation ( $p=.002$ ), follow-up appointments ( $p=.037$ ), and facsimile of discharge summary to PCP ( $p=.004$ ) were effective in reducing the risk-standardized 30-day readmission rate in patients with HF. The evidence indicates that bundled or combination of strategies reduce readmission rate in various populations.

### **Single Transitional Care Intervention**

Although no effective single interventions were identified in a study by Hansen et al. (2011), post discharge telephone calls were frequently included in the bundle intervention which showed a reduction of readmission rates in chronic care patients. Moreover, a telephone follow up was effective in decreasing 3-month ( $p=.05$ ), 6-month ( $p=.014$ ), and 12-month ( $p<.0001$ ) readmission rates among heart failure patients (Lee & Park, 2010). In a prospective study with high risk veterans, the group with telephone intervention had one-third fewer 30-day readmission compared to the control group (Kind et al., 2012). The best practice protocol for transitional care recommends telephone follow up for at least two months post discharge on patients 65 years and older with chronic diseases (Lim, Foust, & Van Cleave, 2012). Although a retrospective study by Kashiwagi, Burton, Kirkland, Cha, and Varkey (2012) revealed that the timing of post discharge

follow-up did not affect readmissions in the general medical patients, Cakir and Gammon's (2010) retrospective chart review showed that scheduling a follow up appointment, as a single intervention, can also reduce readmission rate in patients with chronic illness.

The 2013 report of the American College of Cardiology Foundation and American Heart Association task force on practice guidelines in collaboration with the International Society for Heart and Lung Transplantation suggests that heart failure patients should be given written discharge instructions, a follow-up appointment in seven to fourteen days, and a follow-up telephone call within three days of hospital discharge (Yancy et al., 2013). Also, the guidelines of the Heart Failure Society of America (HFSA) recommend discharge planning to include scheduled follow-up clinic appointments in seven to ten days and follow up telephone calls (HFSA et al., 2010).

### **Nurse, APRN-led Transitional Care Intervention**

One systematic review showed insufficient evidence of a nurse-led HF clinic intervention in reducing HF specific readmissions (Feltner et al., 2014). However, most of the literature reported that nurse-led TCI improved readmission rate (Verhaegh et al., 2014; Stamp et al., 2014; Slyer et al., 2011; Naylor et al., 2004; Naylor et al., 2013; Stauffer et al., 2011; Lee & Park, 2010; and Kind et al., 2012). In a quasi-experimental study, an APRN-led transitional care intervention had a 25% reduction in readmissions compared to the usual care group (Naylor et al., 2013).

### **Cost Effectiveness of TCI**

In a 2012 RCT study, a TCI saved \$1034 per individual (Saleh et al., 2012). The study reported \$1.09 was saved for every \$1 spent on the program. Additionally, in a prospective, non-randomized study, a TCI program saved an average of \$1200 for every avoided readmission and had a 128% return on investment due to reduced readmission rate (Huntington et al., 2013). Even

though a single intervention, a telephone follow up post hospital discharge produced an estimated total savings of \$966,167 or \$1,225 per patient net of programmatic costs (Kind et al., 2012). Transitional care models have shown cost effectiveness in patients with HF. A study found that a TCM had a short-term savings in healthcare cost by \$439 per member per month ( $p < .026$ ) in three months and a total savings of \$2170 ( $p < .037$ ) per patient in the first year (Naylor et al., 2013).

### **Quality of Life and Satisfaction with TCI**

Transitional care intervention improves quality of life (QOL) in HF patients despite wide difference in the intensity of the interventions (Stamp et al., 2014). In addition to quality of life, TCI improves self-efficacy, and satisfaction (Wong et al., 2014). Discharge transition programs have positive effects in patient's self-management skills and abilities (Saleh et al., 2012). The transitional care model improves patient satisfaction, health and functional status, and QOL (Naylor et al., 2004; Naylor et al., 2013). Likewise, HF participants in a study on TCM had significant improvements in functional status, depression, symptoms status, and self-reported health (Naylor et al., 2004).

### **Theoretical Framework**

The theoretical framework of Meleis middle-range transitions theory was utilized to guide the implementation of the transitional care interventions. In the nursing profession, transition has been used as a central concept especially in health related changes and well-beings (Schumacher & Meleis, 1994). In this current study, the transitions theory was beneficial in assisting the APRN, who was the student investigator, to achieve a smooth and effective patient transition from hospital to home. According to Meleis (2010), patients can experience healthy and unhealthy transitions in going home following hospitalization, and patients may encounter

problems during discharge if they are not properly prepared which can lead to readmission. The transitional care intervention may promote healthy transitions.

The transitions theory has four major concepts: nature of transition, transition condition, pattern of response, and nursing therapeutic (Meleis et al., 2000). Based on the theoretical framework (see Appendix B), patients can experience single or multiple changes in health and illness during readmissions and discharges. Engagement depends on the level of awareness (Meleis et al., 2000); patients who are well informed about the nature of their health will apparently engage in their care (Im, 2014). Likewise, a transition can facilitate or hinder an effective transition (Schumacher & Meleis, 1994). The patterns of response are conceptualized as process indicators and outcome indicators (Meleis, 2010). Operationally, in the current study, the response pattern was measured as the rate of 30-day readmission. The nursing therapeutic was the transitional care interventions.

## **Methods**

### **Institutional Board Review, Ethical Issues**

Institutional Review Board (IRB) approval from the medical center and university was obtained (see Appendix G). An expedited review was processed and there was minimal risk to human subjects. The participation by the subjects was solely voluntary, and a copy of the signed informed consent was given to each participant in the intervention group (see Appendix H). In the study, the protection of privacy and data confidentiality of the participants were maintained. The participant's protected health information (PHI) included participant's name, medical record number, telephone number, hospital discharge summary, and records of medication. All information gathered from the participant's electronic record remained confidential in a locked filing cabinet in the student investigator's professional office. Only the principal and student

investigator had access to the participant's PHI. All data were coded to protect participant's information, and the identifiers that matched the participant's name were stored in an encrypted USB and secured in a separate locked drawer. The encrypted USB was destroyed at the conclusion of the study. Additionally, the study observed compliance with the Health Insurance Portability and Accountability Act (HIPAA). As per medical center IRB policy, HIPAA Form B was completed, and the form is a waiver of authorization used in retrospective chart reviews and when subjects will not be contacted.

### **Funding**

Although no funds were received for the study, a cost savings analysis of the TCI was conducted. The study cost \$32,000 for three months. The estimated direct and indirect cost needed for the pilot study was \$28,000 and \$4,000, respectively. Based on Rizzo's (2013) data, each heart failure or all cause readmission costs an average \$12,000 per hospitalization. Based on the number of readmissions in the site department, the estimated three month cost of the hospital readmission would have been \$72,000. The pilot study approximate savings of \$40,000 was projected for a three month period (see Appendix D).

### **Setting and Participants**

The study was implemented in an outpatient medical center in New York City. The Medical Center includes six hospitals with a total bed capacity of 2,478 (New York-Presbyterian Hospital, n.d.). In 2014, the adult heart transplant department had 4,751 outpatient visits (Director of Clinical Operations, personal communication, April 10, 2015). The number of transplanted hearts was 42 in 2014. The project included 18 years and older patients discharged from the medical center with a principal diagnosis of heart transplant, male and female, English speaking, and telephone access. However, patients with psychiatric illness, cognitively impaired,

and discharged to nursing homes were excluded. The total convenience consecutive sampling size of the study was 43 participants.

### **Evidence Based Practice Intervention and Implementation**

In the synthesis review, the term transitional care interventions was interchangeably used with transition care, transitional care model, care transition, care coordination, and discharge planning intervention. During discharge from hospital to home, Boulton et al. (2009) described that most interventions in transitional care will provide patients with smoother, safer, and more-efficient transitions. Evidence from studies show that TCI can reduce readmission rate by improving coordination and communications between providers, patients, and caregivers during transitions. Before implementing the current study, a project timeline was created to guide the student investigator in completing the project within six months (see Appendix E). In the study, the transitional care intervention consisted of four components conducted by the APRN: (1) meeting with the participants at the hospital, (2) facsimiles of discharge summaries, (3) scheduling a follow-up appointments, and (4) telephone call follow-up for 30 days post hospital discharge (see Appendix F). The cardiologists, nurse practitioners, and nurses assisted in identification of eligible participants from the hospital setting. After the potential participants agreed to learn about the study, the APRN met with the participants within 24 to 48 hours before hospital discharge to explain the study and obtain consent. The meeting proceeded with the discussion on the nature and severity of illness and was followed by a review of the participants' health behaviors and skills, and social support. The meeting took about 30 minutes depending on participant and participant's caregiver level of comprehension.

Within 48 hours after the participants were discharged from the hospital, a copy of the discharge summary was faxed to the primary care provider or transplant cardiologist. A follow-

up appointment with the transplant cardiologist or PCP within seven to ten days post discharge from the hospital was arranged, and the information was provided to the participant. This activity took 15 to 30 minutes depending on waiting time on the phone.

Within 48 hours after the participants were discharged from the hospital, a telephone follow up was conducted by the student investigator who assessed patients overall health status; reviewed signs and symptoms of cardiac rejection and infection, home vital signs, medication's adherence and side effects; and reiterated the contact number to call for urgent and emergency issues. The telephone follow up took 15 to 30 minutes with some of the initial calls exceeding this time allotment. For four weeks, each participant received two follow up telephone calls a week. An intervention checklist and a telephone script were used to assess compliance of participants with the transitional care intervention program, thus enhancing consistency and adherence to the intervention (see Appendix I).

### **Change Theory**

An advanced practice registered nurse can be a change agent in implementing a new intervention in an organization. The study utilized Kurt Lewin's theory of planned change (TPC) in planning and implementing the project. The three-step process in Lewin's TPC includes unfreezing, moving or transitioning, and refreezing (Shirey, 2013). Lewin's TPC uses the idea of equilibrium within the system. To create the change, the change agent must break the equilibrium by altering the relative strengths of driving and restraining forces. In the current study, the unfreezing stage began when the APRN identified the problem, and recognized and mobilized others to see the need for change and the interventions selected. During the stage of moving or transitioning, a detailed plan of action was created and other healthcare members were



engaged to participate in the study. In the refreezing stage, stabilizing and evaluating the study sustainability was essential.

### **The Model for Evidence-Based Practice Change**

The Model for Evidence-Based Practice Change was selected to guide the development of the study. According to Rosswurm and Larrabee (1999), the model provides framework for integrating evidence-based interventions into practice. The six steps of the model include assessing the need for change in practice, identifying the best evidence, critically analyzing the evidence, designing practice change, implementing and evaluating change in practice, and integrating and maintaining change in practice (Melnyk & Fineout-Overholt, 2011). The model was derived from a combination of quantitative and qualitative data, clinical expertise, and contextual evidence and was tested for usefulness in nursing and applied in primary care and acute care settings (Rosswurm & Larrabee, 1999). The current study was implemented in an outpatient clinic at a medical center by an APRN, and the EBP model was simple, practical, and easy to understand. The key actions in each step were clear, applicable to the study, and provided a systematic process in implementing the new intervention.

### **Study Design**

The design of the study was quasi-experimental with comparison between the intervention group and the usual care group. The two groups included patients who received the TCI and patients who had routine usual discharge care. This current study utilized retrospective data as the baseline, usual care group. The primary outcome measured was the 30-day readmission rate before and after the transitional care intervention.

### **Validity**

Numerous factors could have impacted the outcome of the study. Selection bias was a major concern that could affect the study results because of non-randomization although convenience sampling was used. To promote internal validity, the study included baseline data and intervention data. One APRN conducted the intervention for consistency. To prevent attrition, the participation of the subjects was solely voluntary. An intervention checklist and a telephone script were used to promote and assess participant compliance with the TCI program. The study was a pilot study, and power was not determined prior to the study.

Difference in the participant's characteristic could have affected the outcomes of the study. The inclusion and exclusion criteria of the study promoted homogeneity. Review of the participant's demographics in the baseline and intervention data for similarity enhanced internal validity. The student investigator was also involved in collecting the data, and constant self-assessment for introduction of biases was addressed. Because the demographics were similar in the study and represented a specific population, generalizability outside of the study target population may be limited although in the published research, the TCI was implemented in various populations. The study can potentially apply to other populations with similar characteristic and setting such as patients with chronic medical-surgical illnesses with hospitalization and follow-up in the out-patient setting.

### **Outcomes Measured**

The primary outcome measure of the study was the 30-day readmission rate post hospital discharge in cardiac transplant patients. Measurement of 30-day readmission rate is recommended by the Centers for Medicare and Medicaid Services (CMS). CMS explained that readmission over an extended time period may be affected by factors outside the hospital control. The implementation of the TCI was intended to have a positive impact on readmission to the

hospital within 30 days. The major outcome of the study was to improve the quality of care and reduce cost in the healthcare system (see Appendix C). Potential secondary outcomes, which were not measured due to the limited time length of the study included mortality, cost effectiveness, and QOL and patient satisfaction.

### **Measurement Instruments**

The study measurement was the 30-day readmission rate as indicated in the paper and electronic health record (EHR). A patient may have readmitted to another hospital without transfer to the project site hospital which would be a threat to the accuracy of the 30-day readmission data. Baseline usual care group and intervention group demographic variables were collected to assess the similarity of the groups (see Appendix J).

### **Quality of Data**

The study utilized the medical center's EHR and paper chart for the demographic data. For the retrospective baseline, data from September 2013 to March 2014 was reviewed and collected. This was patterned with the prospective group time frame of September 2015 to March 2016. Missing of important data such as participants readmitted to other centers was a concern. Inclusion and exclusion criteria were established. The usual and intervention groups had a combined greater than 30 participants and a power analysis was calculated. With  $n$  (sample) =43,  $\alpha$  (alpha) =0.05,  $df$  (degree of freedom) =1, and  $w$  (medium effect) =0.3, the post hoc analysis revealed a  $1-\beta$  (power) of 0.50. Based on chi-square power analysis calculation, a number of 88 participants was required to achieve a power of 80% or 0.80 for chi square test with a medium effect size ( $w=0.3$ ).

### **Analysis of Data**

An excel spreadsheet was created to record the data collected, and SPSS software was used for statistical analysis. The study included descriptive and inferential statistics. In descriptive analysis, the demographic variables were reviewed for characteristics and similarities. A chi-square was used for statistical analysis of the baseline and intervention group data categorical variables and independent *t*-test for continuous variables. The chi-square statistic was used in answering the study question about the presence of a statistically significant relationship between transitional care intervention (usual/intervention) and 30-day readmission rate (yes/no).

In addition, a Fisher's Exact Test was calculated because the sample size was small, marginal was uneven, and a value of less than five in one of the cells. The quantitative data that was collected and analyzed to determine the success of the transitional care intervention included tracking the readmissions within 30 days for patients receiving the TCI. The student investigator collaborated with a statistician on statistical analysis. A result of  $p < 0.05$  was considered statistically significant.

## **Results**

### **Setting & Participants**

For six months, the study was conducted at the cardiac transplant outpatient medical center in New York. The total sample size was 43 (intervention group  $n = 24$ , usual group  $n = 19$ ). The participants in the study were diverse: 42% were white, 30% were black, 16% were Hispanic, and 12% were Asian descent. The average age of the participants was 55.9 years old with 23 participants aged 41-64 years, 33 participants (77%) were male, 26 (60.5%) participants were married, and 27 participants (62.8%) had graduated from high school. Further examination of the demographic characteristic of the two groups revealed that 49% of the participants were 1-

5 years post-cardiac transplant, and 33% were more than 6 years. More than half (58.3%) of the participants in the intervention group were treated for infection during hospital discharge.

Almost half (47.4 %) in the usual group received treatment of rejection. The cardiac transplant participants also had chronic diseases: 32 (74%) participants suffering from hypertension, 34 (79%) with hyperlipidemia and 31 (72%) with diabetes mellitus (all types).

The two groups were compared using a chi-square or Fisher's Exact test for categorical variables and an independent *t*-test for continuous variables. Although the participants in intervention group had a higher percentage of hypertension compared to the usual group, 95.8% vs 47.4%, respectively ( $p=0.001$ ), all the other co-morbidities were not statistically different between the groups ( $p>0.27$ ; see Appendix J). Also, no significant differences were found between the two groups with respect to demographic characteristics (see Appendix L).

### **Intervention Course, Actual**

In the intervention group, a total of 24 participants completed the study. Two participants were readmitted for rejection and infection within 30-day post hospital discharge. The transitional care intervention four components were implemented: meeting with the participants, faxing of discharge summaries, scheduling follow up appointments, and telephone call follow-ups. Each participant in the intervention group received the transitional care intervention for 30 days post hospital discharge. For the usual care group, 19 participants were selected from a retrospective chart review from September 2013 to March 2014. Seven participants were readmitted during the 30-day post hospital discharge. During the retrospective review, there were inconsistent data on hospital discharge date and readmission date. As a result, potential participants with missing data of more than 30% were eliminated from the data collection.

### **Outcome Data by Sub-Topic**

The transitional care intervention showed improvement in the 30-day readmission rate in cardiac transplant patients. In the study, the intervention group had a 30-day readmission rate of 8.3% (2/24) compared to 36.8% (7/19) in the usual group (see Appendix M). Overall, results indicated a significant difference ( $p=0.03$ , Fisher's Exact test) in the 30-day readmission rate among cardiac transplant patients, with a larger proportion of readmissions encountered in the usual care group (see Appendix K). The TCI intervention resulted in significantly less 30 day readmissions as compared to usual care.

## **Discussion**

### **Successes, Most Important**

Although challenges were present in conducting the study and collecting the data, the findings were promising in the small sample size. In patients with cardiac transplant, the transitional care intervention showed significant improvement in the 30-day readmission rate ( $p=0.03$ ). The demographic variables in both groups were similar.

### **Study Strengths**

The study was implemented in an outpatient medical center in New York City. The organization culture was consistent with the desired setting for the study. The organization supports excellence in patient care, research, education and community service (NYPH, n.d.). The administrator and medical director of the heart failure and heart transplantation fully supported the project. The transplant cardiologists and nurses were helpful in recruiting study participants. Electronic health records as well as paper charts were available for data collection. In the intervention group, no participants withdrew during the study. The initial 24 participants completed the transitional care intervention within 30 days post hospital discharge. Overall, the implementation of the study was successful.

## Results Compared to the Evidence in the Literature

In published studies, the TCI was implemented in different populations. Although the TCI structures varied, there were similarities in the published results to the current study findings. The systematic review by Leppin et al (2014) found that interventions with multiple components were more effective than single interventions in medical and surgical patients. In the current study, the four components of the TCI showed improvement in the 30-day readmission rate in cardiac transplant patients. Likewise, the systematic review by Verhaegh et al. (2014) indicated that care coordination by a nurse, and communication between the hospital and the PCP was significantly ( $p<.05$ ) associated with reduced short-term readmission rates in 60 years and older patients with chronic illness. In addition, the outcome of the current study was parallel with findings from the quasi-experimental pre-post study by (Dedhia et al., 2009). At 30 days, Dedhia et al. found that the intervention group had a lower rate of readmission (22% vs 14%). Similarly, the current study showed that the intervention group had a 30-day readmission rate of 8.3% compared to 36.8% in the usual group. Furthermore, the retrospective cohort study of Jackson et al. (2013) revealed that the participants from the transitional care had 20% lower adjusted readmission rates compared to usual care.

In the synthesis review for the current study, nurse-led TCI improved readmission rates (Verhaegh et al., 2014; Stamp et al., 2014; Slyer et al., 2011; Naylor et al., 2004; Naylor et al., 2013; Stauffer et al., 2011; and Lee & Park, 2010). Similar to other published studies, the current study was successfully led by an advanced practice registered nurse. Nurse-led TCI is effective because of the continuity of care and the holistic use approach by the APRN (Naylor et al., 2004). There was one APRN conducting the intervention for consistency in the current study. In a quasi-experimental study by Naylor et al. (2013), an APRN-led transitional care had a 25%

reduction in readmissions compared to the usual care group. Likewise, the APRN-led study showed that the intervention group had a 30-day readmission rate of 8.3% compared to 36.8% in the usual group.

### **Limitations**

In the study, the group who received the transitional care intervention had a lower 30-day readmission rate compared to the group who had usual care. Although findings of the study highlight the efficacy of the TCI, several limitations and threats to validity were identified. Missing data was encountered and included readmission to other healthcare centers. Specifically, when a patient readmitted to another hospital without transfer to the project site hospital, the information was not captured in the medical record which posed a threat to the accuracy of the 30-day readmission data. There were eligible patients who declined enrollment. The pilot study sample size was 43 and power was not achieved. Because of non-randomization, selection bias could have affected the study results. Although the participants' characteristics were similar, differences in the participants' physical capacity and support system could also alter the results of the study. This was an outcome study, so there was no data to inform which four components of the TCI brought the effects. The study did not include a cost-effective analysis of the 30-day readmission outcome.

In addition, the study was conducted in a single academic medical center and results may not be able to generalize patients in other settings. In the study, heterogeneity was an issue, and the study had similar demographics and represents a specific population. TCI was implemented in different populations in published studies, and the current study TCI can potentially apply to other populations with similar characteristics and settings including patients with chronic medical-surgical illnesses who are receiving outpatient healthcare. To promote validity, there



was one APRN conducting the intervention for consistency in the usual and intervention groups. The intervention checklist and telephone script were valuable in maintaining consistency and completion in the TCI program. In addition, the inclusion and exclusion criterion were essential in promoting similarity and homogeneity of the study. Because of the investigators' involvement in collecting the data, constant self-assessment for introduction of biases was observed.

### **Interpretation**

**Expected & actual outcomes.** The expected outcome of the study was achieved. In spite of the small sample size, the TCI showed improvement in the 30-day readmission rate in patients with cardiac transplant. There was a statistically significant difference observed between TCI and the usual care group on 30-day readmission ( $p=0.03$ , Fisher's Exact test) which indicated that the four components of the TCI were effective in reducing 30-day readmission.

**Intervention's effectiveness (inferences).** Studies found TCI can reduce readmission rate in different populations. Evidence has shown that TCI can be applied in patients with chronic illnesses. In the current study, the TCI was effective and applicable in the cardiac transplant population. The TCI revealed statistically significant improvement in the 30-day readmission rate ( $p=0.03$ ). The TCI was practical and useful in an outpatient setting. It was implemented by an APRN using simple and easy to follow steps.

**Intervention revision.** Although the outcome of the study was statistically significant, extending the study to one year could potentially involve 88 participants to achieve a power of .80. In addition to measuring the 30-day readmission rate, it would be beneficial if the participant's level of satisfaction and self-management skills were included in the outcome measurements. Potential secondary outcomes include measuring mortality, cost effectiveness, and QOL and could be measured if the time period of the study were extended past 3 months.

**Expected and actual impact to health system, costs, and policy.** The TCI was associated with positive change in the 30-day readmission rate among cardiac transplant patients. The magnitude of the relationship between TCI and 30-day readmission rate as compared to usual care group was statistically significant in cardiac transplant patient ( $p=0.03$ ). Implementing the TCI may reduce 30-day readmission rate in cardiac transplant patients. The participants in the intervention group had a smoother, safer, and more-efficient transition from hospital to home. The four components of the TCI improved coordination and communications between providers, patients, and caregivers during transitions. Compared to the usual group, the participants who received the TCI had reduced 30-day readmission rate. The outcome of the study can provide a positive impact in the healthcare quality, cost, and policy. The study supports the Hospital Readmission Reduction Program (HRRP) of the Patient Protection and Affordable Care Act policy. In the Crossing the Quality Chasm report, the IOM proposed six aims for improvement of health care system (IOM, 2001). Prevention of readmission is one strategy that aligned with the IOM report. This strategy can improve the quality of care and reduce healthcare cost. For this reason, the outcome of the study will benefit the cardiac transplant department by avoiding penalty, decrease payments, and loss of revenues from Medicare. Although the study does not have funding sources, several grant/scholarship applications were submitted and potential future grand funding may be possible.

### **Conclusion**

Studies found transitional care intervention (TCI) can reduce readmission rate in different populations. Evidence shows that TCI can be applied in patients with chronic illnesses such the cardiac transplant patients. TCI is practical and useful in the clinical arena and can be implemented by an APRN using simple and easy to follow steps. The implementation of TCI

also fosters interprofessional collaboration by relaying information to primary care physician or cardiologist in a timely manner. Further study of the intervention should include measurement of 90, 180, and 360-day readmission rate. Use of a larger sample size and randomization in future studies can be beneficial. Future studies should include the cost-effectiveness, quality of life, satisfaction, and self-management skills and abilities associated with this intervention.

Dissemination can facilitate other clinicians change to evidence based practice and positive improvement of patient care. Last October, 2015, an evidence based proposal e-poster was presented at the Nurse Practitioner Association of New York State- 31st Annual Conference. In addition, an abstract was submitted to the “2016 Ninth National Doctors of Nursing Practice Conference” in Baltimore for presentation, and a manuscript will also be submitted to a peer reviewed nursing journal in order to foster evidence based TCI by increasing awareness by nurses and advanced practice nurses on TCI benefits.

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## Appendix A

## Review of Evidence Table

First author, Year, Title, Journal	Purpose	Research Design, Evidence Level <sup>2</sup> & Variables	Sample & Sampling, Setting	Measures & Reliability (if reported)	Results & Analysis Used	Limitations & Usefulness
Verhaegh et al. (2014)  Transitional care interventions (TCI) prevent hospital readmissions for adults with chronic illnesses  <i>Health Affairs</i>	To examine if TCI interventions were associated with a reduction of readmission rates in the short (30 days or less), intermediate (31–180 days), and long terms (181–365 days)	SR Quantitative /Meta-analysis  Level 1  Readmission (short, intermediate, long-term) TCI (low and high intensity)	26 RCT's  Total-7932  Intervention-3992 Control- 3940  60 years and older, single-center	Heterogeneity  Utilized reporting items for systematic Reviews and Meta-analysis (PRISMA) guidelines.  Odd ratios, absolute risk reduction, and p-value were calculated	TCI was associated with reduced intermediate-term (31–180 days) and long-term (181–365 days) all-cause hospital readmissions of chronically ill patients.  In high intensity intervention, the absolute risk reduction was 5 percent for short-term, 7 percent for intermediate-term, and 13 percent for long-term readmissions.	Studies measured readmission with various diagnoses  Home visit within three days, care coordination by a nurse and communication between the hospital and the primary care provider were components of TCI that were significantly associated with reduced short-term readmission rates.  Feasible
Stamp, Machado, and Allen (2014)  Transitional care programs improve outcomes for heart failure patients  <i>Journal of Cardiovascular Nursing</i>	To examine interventions, quality of life, and readmission rates of individuals with heart failure who are enrolled in a transitional care program.  To examine the cost-effectiveness of nurse-led transitional care program	Integrative Review  Level 1	Out of 20 studies, 19 included readmission rates. Quantitative and Qualitative research focused on discharge planning and follow up of HF patients 18 years or older. English, Peer reviewed Sample sizes-70-1023 participants Included TCI and usual care from 10 days to 180 months	58% of the studies were rated high intensity intervention  21% moderate  21% low intensity	Multidisciplinary nurse-led inpatient education and counseling, home visits alone or in combination with telephone calls-were successful intervention in decreasing readmission.	Great variability in the programs  Co-morbidities not accounted.  Few studies on QOL, measurement of cost varied.  Nurse-led TCI positive influence in readmission rate, quality of life, and healthcare cost.  Useful
Leppin et al. (2014)  Preventing 30-Day Hospital Readmissions  <i>JAMA Internal Medicine</i>	To review the evidence of the effectiveness of interventions to reduce early hospital readmissions and identify intervention feature that includes impact on treatment burden and on patients' capacity to enact post discharge self-care and their varying effects	SR Quantitative with Meta-analysis.  Level 1  Discharge Interventions, 30-days Readmission, Treatment burden, post discharge self-care	42 RCT studies  Adult patients hospitalized for a medical or surgical cause for more than 24 hours and discharged to home.	Less heterogeneity  Prevented early readmissions (pooled random-effects) $P < .001$ . Studies before 2002-intervention more effective In subgroup analysis, interventions with many components-more effective	Most discharge interventions tested are effective in reducing the risk of early readmissions  The discharge intervention was effective in reducing the readmission rate	Single academic centers.  Many eligible patients declined enrollment in some studies  Useful

First author, Year, Title, Journal	Purpose	Research Design, Evidence Level2 & Variables	Sample & Sampling, Setting	Measures & Reliability (if reported)	Results & Analysis Used	Limitations & Usefulness
<p>Slyer, Concert, Eusebio, Rogers, and Singleton (2011)</p> <p>A systematic review of the effectiveness of nurse coordinated transitioning of care on readmission rates for patients with heart failure (HF)</p> <p><i>JBI Library of Systemic Review</i></p>	<p>To identify the best available evidence on the effectiveness of nurse coordinated transitioning of care between hospital and home on hospital readmission rates for all causes in adult patients hospitalized with HF.</p>	<p>SR Quantitative/ Meta-analysis</p> <p>Level 1</p> <p>Nurse, HF, Readmission</p>	<p>16 RCT</p> <p>18 years and older, hospitalized with HF and discharge to home.</p> <p>Studies were from the US, Canada, Europe, Australia, Asia</p> <p>TCI were all carried or coordinated by a nurse.</p>	<p>Table of description of the TCI included.</p> <p>Overall: Telephone (p=0.2802) Home visit (p=0.0192) Telephone and Home visit combined (p=0.0628)</p>	<p>Ten of the 16 studies included in the review show that a nurse led transitioning of care intervention can reduce the rate of readmission for patients with HF</p> <p>Interventions utilizing home visits, or home visits coupled with telephone follow-up, show a more favorable reduction in readmission rates.</p>	<p>Small samples studies Heterogeneity Mainly on older adults Lack of current research</p> <p>Nurse-led transitional care who conducts at least one home visit and follow up with telephone contact reduced readmissions rate</p> <p>This study will support my project.</p>
<p>Feltner et al. (2014)</p> <p>Transitional care interventions to prevent readmissions for persons with heart failure</p> <p><i>Annals of Internal Medicine</i></p>	<p>To assess the efficacy, comparative effectiveness, and harms of transitional care interventions to reduce readmission and mortality rates for adults hospitalized with HF</p>	<p>SR Quantitative/ Meta-analysis</p> <p>Level 1</p>	<p>47 RCT'S</p> <p>Usual care versus home visit, telephone support, telemonitoring, outpatient clinic-based, educational, peer support, cognitive training)</p> <p>Most enrolled adults with moderate to severe HF and a mean age of 70 years.</p> <p>Few trials reported 30-day readmission rates</p>	<p>Table was included describing the strength of evidence.</p> <p>Home visit, STS, MDS-HF clinic-moderate to high effective in 3-6 months all cause readmission</p> <p>Home visit, STS, telemonitoring-moderate to high effective in 3-6 months HF-specific readmission</p>	<p>Home-visiting programs and MDS-HF clinics reduced all-cause readmission and mortality</p> <p>STS reduced HF-specific readmission and mortality.</p> <p>These interventions should receive the greatest consideration by systems or providers seeking to implement transitional care interventions for persons with HF.</p>	<p>Many of the included trials had methodological limitations</p> <p>Few trials reported 30-day readmission rates.</p> <p>Heterogeneity of outcome measures</p> <p>STS and MDS-HF would be beneficial to my project</p>

First author, Year, Title, Journal	Purpose	Research Design, Evidence Level2 & Variables	Sample & Sampling, Setting	Measures & Reliability (if reported)	Results & Analysis Used	Limitations & Usefulness
Hansen, Young, Hinami, Leung, and Williams (2011)  Interventions to reduce 30-day rehospitalization: a systematic review.  <i>Annals of Internal Medicine</i>	To describe interventions evaluated in studies aimed at reducing rehospitalization within 30 days of discharge	SR  Level I	43 studies in all 24 studies single intervention 12 studies-bundle	Cochrane Effective Practice and Organization of Care (EPoC) Group's Risk of Bias Criteria	Meta-analysis were not feasible, there were no effective single interventions in the study  Telephone calls were frequently included in the RCT's that had shown the effectiveness of bundle intervention in reducing readmission rate	Inadequate description of individual studies interventions, single institution assessment quality improvement rather than experimental, and several common interventions have not been studied outside discharge bundles  Useful
Wong, Chow, Chan, and Tam (2014)  Comparison of effects between home visits with telephone calls and telephone calls only for transitional discharge support  <i>Age Ageing</i>	To examine the overall effects of a transitional care program for discharged medical patients and the differential effects of telephone calls only	RCT  Level II  Home visit, telephone call, readmission, quality of life, self-efficacy, satisfaction	610 participants from medical unit Control-210 Home visit and telephone- 196 telephone- 204 Regional Hospital in Hong Kong	After 4 weeks and 12 weeks. Home visit- (10.7%, 21.4%), Telephone- (11.8, 20.6%) had lower readmission rates than the Control group- (17.6, 25.7%).	Home visit and Telephone call lower readmission rate. Although combined home visit and telephone call is more effective. Significant improvement in quality of life, self-efficacy and satisfaction in both ITT and PPA for the study groups	Limit generalization-conducted among patients with chronic diseases in a regional hospital in Hong Kong. No data to inform which part of the intervention process that brings about the effects. Bundled intervention-more effective
Saleh, Freire, Morris-Dickinson, and Shannon (2012)  An Effectiveness and Cost-Benefit Analysis of a Hospital-Based.  <i>Journal of the American Geriatrics Society</i>	To investigate the business case of post discharge care transition (PDCT) among Medicare beneficiaries by conducting a cost-benefit analysis.	RCT  Level II	Elderly Medicare beneficiaries being treated from October 2008 through December 2009.  Intervention— 173 Regular discharge-160 followed for 12 months.  A general hospital in upstate New York	Cost-benefit ratio of the PDCT program; self-management skills and abilities.  Control versus intervention - (58.2% vs 48.2%; P = .08  Cost-benefit analysis revealed a cost-benefit ratio of 1.09, which indicates that, for every \$1 spent on the program, a saving of \$1.09 was realized. In addition,	1-year readmission analysis revealed that control participants were more likely to be readmitted than intervention. With most of that difference observed in the 91 to 365 days after discharge.  Cost-effective  Transition program significantly enhanced self-management skills and abilities.	Other cost not analyzed Single hospital Self-management skills- not validated  The transitional intervention include: development of a patient-centered health record, a structured discharge preparation checklist of critical activities, delivery of patient self-activation and management sessions, follow-up appointments, and coordination of data flow.

First author, Year, Title, Journal	Purpose	Research Design, Evidence Level2 & Variables	Sample & Sampling, Setting	Measures & Reliability (if reported)	Results & Analysis Used	Limitations & Usefulness
<p>Naylor et al. (2004) Transitional care of older adults hospitalized with heart failure. <i>Journal of the American Geriatrics Society</i></p>	<p>To examine the effectiveness of a transitional care intervention delivered by advanced practice nurses (APNs) to elders hospitalized with heart failure.</p>	<p>Multisite-RCT with follow-up through 52 weeks post hospital discharge  Level II  Transitional care, readmission, death, quality of life, functional status, costs, and satisfaction with care.</p>	<p>239 patients Control-121 Intervention -118  65 years and older and hospitalized with heart failure.  6 Philadelphia academic and community hospitals.</p>	<p>Time to first readmission or death was longer in intervention patients (P =.026)  At 52 weeks, intervention group patients had fewer readmissions (P=.047)  Lower mean total costs (\$7,636 vs \$12,481, P=.002).  For intervention patients, only short-term improvements were demonstrated in overall quality of life ( P&lt;.05), physical dimension of quality of life ( P&lt;.01; 12 weeks, P&lt;.05) and patient satisfaction ( P&lt;.001)</p>	<p>A comprehensive TCI for elders hospitalized with heart failure increased the length of time between hospital discharge and readmission or death.  Reduced total number of readmission and decreased healthcare costs</p>	<p>Older studies but very useful- because of its multisite RCT.  Not only it showed how TCI reduce readmission but also the economic effectiveness.  This study is useful and beneficial to my project.</p>
<p>Huntington, Guzman, Roemen, Fieldsend, and Saloum (2013)  Hospital-to-Home: a hospital readmission reduction program for congestive heart failure.  <i>South Dakota medicine: Journal of the South Dakota State Medical</i></p>	<p>To decrease the 30-day readmission rate following hospital stay for congestive heart failure</p>	<p>Prospective, Non-randomized, Two-center pilot project  Level III</p>	<p>Out of 250 eligible patients, 98 consented to enroll.  General hospital and cardiac specialty hospital, Rural South Dakota.  All patients 18 years and older admitted between June 7, 2010 and June 6, 2011 with a diagnosis of primary or secondary congestive HF.  With access to a telephone in the home care setting</p>	<p>Fisher's Exact Test  30-day all-cause readmission (p=0.043)  Medication reconciliation (p=0.038)  Timely follow up (p&gt;0.05)  Educational intervention (p&lt;0.001)</p>	<p>A statistically significant 42 percent relative reduction in 30-day readmission rate.</p>	<p>Not randomized, blinded or placebo controlled.  Selection bias  Study population was limited  An intensive transition of care program decreases the 30-day readmission rate for patients with congestive heart failure in a non-urbanized Midwestern state like South Dakota.  Useful</p>

First author, Year, Title, Journal	Purpose	Research Design, Evidence Level2 & Variables	Sample & Sampling, Setting	Measures & Reliability (if reported)	Results & Analysis Used	Limitations & Usefulness
Dedhia et al. (2009)  A quality improvement intervention to facilitate the transition of older adults from three hospitals back to their homes.  <i>Journal of American Geriatrics Society</i>	To study the feasibility and effectiveness of a discharge planning intervention	Quasi-experimental pre-post study design  Level III	237 participants-pre  185-intervention  65 years and older admitted to the hospitalist services  General medicine  Academic center, community teaching hospital, community-based non-teaching hospital	Thirty-day readmission and return to emergency department rates and patient satisfaction with discharge	Intervention had lowered return to the emergency department within 3 days of discharge (10% vs 3%). At 30 days, Dedhia et al. (2009) found that the intervention group had lower rate of readmission rate (22% vs 14%) and fewer visits to the emergency department (21% vs 14%)	Non-randomized controlled trials, and possible effect of seasonal variation on the results. The interventions included were facsimile patient discharge summary to the primary care provider, interdisciplinary worksheet to identify barriers to discharge, medication reconciliation, and follow up appointments
Naylor et al. (2013)  High-value transitional care: translation of research into practice  <i>Journal of Evaluation in Clinical Practice</i>	To evaluate the impact of translating into a large US health plan, the Transitional Care Model (TCM), an evidence-based approach to address the needs of chronically ill older adults throughout acute episodes of illness	Prospective, Quasi-experimental study  Level III  TCM, re-hospitalization, health resource utilization, and cost outcomes	172 at-risk Aetna Medicare Advantage members in the mid-Atlantic region who received the TCM.  Oct 15 2006-April 30, 207.  Cognitively intact. 65 years and older Chronic illness Reachable by phone.	Decrease in number of re-hospitalizations (45 vs. 60, $P < 0.041$ ) and total hospital days (252 vs. 351, $P < 0.032$ )  The TCM was associated with a short-term decrease of \$439 per member per month in total health care costs at 3 months and cumulative per member savings of \$2170 at 1 year ( $P < 0.037$ )	Improvements in all health status and QOL measures were observed in post-intervention.  Decrease in number of re-hospitalizations and total hospital day in 3 months.  Reductions in other utilization outcomes or time points were not statistically significant.  Cost effective	Health status, QOL and satisfaction data were available from only the intervention group.  The matched control group that was selected obtained from a geographic area which had a 20% lower acute care utilization rate at baseline as compared to the mid-Atlantic region
Stauffer et al. (2011)  Effectiveness and cost of a transitional care program for heart failure: a prospective study with concurrent controls.  <i>Archives of Internal Medicine</i>	To assess the effectiveness of an APN-led TCP for recently hospitalized patients with HF and to determine the impact of this TCP on the 30-day (from discharge) all-cause readmission rate, LOS, and 60-day (from admission) direct cost.  To perform budget analysis	Prospective study with concurrent control  Pilot study  August 24, 209-April 30, 2010  Level IV	65 years old and older-HF patients  Medical Center	Adjusted Value-95%CI 30-days Readmission Before intervention-25.2 After intervention- 12.6	The intervention significantly reduced adjusted 30-day readmission rates to 48%. The intervention had little effect on LOS or total 60-day direct costs. Under the current payment system, the intervention reduced hospital financial contribution margin on average \$227 of each Medicare.	Observational study Although adjustment was done- possibility of unmeasured difference. 25% admit to nursing home-not reached by intervention. The impact of the APN-led TCP for HF patients on LOS and 60-day direct costs was minimal, but the TCP significantly reduced 30-day readmission rates

First author, Year, Title, Journal	Purpose	Research Design, Evidence Level2 & Variables	Sample & Sampling, Setting	Measures & Reliability (if reported)	Results & Analysis Used	Limitations & Usefulness
<p>Jackson, Trygstad, DeWalt, and DuBard (2013)</p> <p>Transitional care cut hospital readmissions for North Carolina Medicaid patients with complex chronic conditions</p> <p><i>Health Affairs</i></p>	<p>To evaluate the effectiveness of this large-scale program in reducing readmissions for patients with complex chronic conditions during the first year following hospital discharge.</p> <p>To examine one-year readmission rates for patients who received transitional care compared to usual care.</p> <p>To assess whether patients with differing degrees of risk and conditions of varying levels of severity responded differently.</p> <p>To examine readmission rate trends among North Carolina Medicaid beneficiaries with chronic conditions during the five years since the start of the transitional care initiative</p>	<p>Retrospective Cohort study</p> <p>Level IV</p>	<p>21, 375 Medicaid eligible of any age with complex chronic condition</p> <p>Discharged alive from an in-state general hospital with a qualifying DRG code during the period July 2010–June 2011</p> <p>Enrolled in a Community Care of North Carolina primary care medical home at the time of discharge or within thirty days of discharge</p>	<p>Stratified analyses</p> <p>Wilcoxon-Gehan Statistic</p> <p>Cox proportional hazards regression model</p>	<p>Adjusted readmission rates were 20 percent lower for Medicaid beneficiaries who received transitional care within thirty days of discharge than for clinically similar beneficiaries who received usual care.</p> <p>Twelve-month readmission rates were consistently lower for participants within each of the eight strata of clinical severity examined.</p> <p>One readmission was averted for every six patients who received transitional care services and one for every three of the highest-risk patients</p>	<p>Observational study</p> <p>Selection bias</p> <p>Endogeneity issues</p> <p>Intent to treat model</p> <p>Stratifying participants</p> <p>Beneficial study</p>
<p>Bradley et al. (2013)</p> <p>Hospital Strategies Associated With 30-Day Readmission Rates for Patients With Heart Failure</p> <p><i>Circulation Cardiovascular Outcomes</i></p>	<p>To identify what specific strategies to use in reduction of readmission rate for patients with HF</p>	<p>Cross sectional study using web-based survey</p> <p>Level VI</p>	<p>599 participants from 658 hospitals</p>	<p>Six strategies associated with hospital risk-standardized 30-day readmission rate (RSRR)</p>	<p>That single strategies had a modest effect compared to hospitals that implemented a combination of more than one strategy (reduction of 0.34 percentage point for each additional strategy)</p>	<p>Cross sectional study, limited information on the methods of implementation, no assessment of socioeconomic patients profiles, hospital in the study were self-selected, and unable to assess the organizational culture in this quantitative study</p> <p>Beneficial</p>

First author, Year, Title, Journal	Purpose	Research Design, Evidence Level2 & Variables	Sample & Sampling, Setting	Measures & Reliability (if reported)	Results & Analysis Used	Limitations & Usefulness
<p>Cakir and Gammon (2010)</p> <p>Evaluating readmission rates: How can we improve?</p> <p><i>Southern Medical Journal</i></p>	<p>To detect the readmission rates of a hospitalist group at a community hospital</p> <p>To identify probable causes of rehospitalizations, and to propose solutions to decrease the rate of readmissions</p>	<p>Retrospective medical review</p> <p>Level VI</p>	<p>5,206 patients who were admitted to the hospitalist service over one year. 85 (1.6%) were rehospitalized within 30 days due to the same condition. Of the 85 readmitted patients, 47% were male and 82% were Caucasian, with a mean age of 58 ± 17 years.</p>	<p>27% of patients had follow appointments, and 99% received an accurate medication list on discharge.</p> <p>Only 4.7% or readmission were preventable.</p> <p>Follow-up appointments were made for only 27% of patients at first admission</p>	<p>Readmission rate (1.6%) is significantly lower than that of previous studies (23.2%)</p> <p>Patient education, family involvement in discharge process, and scheduling follow-up appointments could potentially reduce readmissions.</p>	<p>Lack of data related to all cause readmission, only subgroup of readmission were included, admission to other hospital, unknown cases, small sample size, and single community hospital</p> <p>Useful</p>
<p>Kashiwagi, Burton, Kirkland, Cha, and Varkey (2012)</p> <p>Do Timely Outpatient Follow-up Visits Decrease Hospital Readmission Rates?</p> <p><i>American Journal of Medical Quality</i></p>	<p>Primary objective of this study was to compare the frequency of unplanned readmissions among patients with follow-up appointments made within 14 days of discharge, those with follow-up appointments scheduled 15 days or more after discharge, and those with no follow-up scheduled.</p> <p>Secondary objectives included comparing age, sex, length of stay (LOS), and Charlson comorbidity index (CCI) among these 3 groups.</p>	<p>Retrospective analysis</p> <p>Level IV</p>	<p>1627 patients admitted to the hospitalist</p> <p>48% male, 92% Caucasian, mean average of 62 years old, and 11% unplanned and 3% planned readmission</p> <p>General medical patients from an academic medical center</p>	<p>Fischer exact test</p> <p>2 sample t-test</p>	<p>No statistical difference in 30-day readmissions between patients with follow-up within 14 days and follow-up 15 days or longer from discharge (<math>P = .36</math>) or between patients with follow-up within 14 days and without scheduled follow-up (<math>P = .75</math>)</p>	<p>Insufficient data on the number of patients who kept their appointments, single academic medical center, ethnically homogeneous population, discharge to group homes and assisted living, readmission to other institution</p>



First author, Year, Title, Journal	Purpose	Research Design, Evidence Level2 & Variables	Sample & Sampling, Setting	Measures & Reliability (if reported)	Results & Analysis Used	Limitations & Usefulness
<p>Lee and Park (2010)</p> <p>The effectiveness of telephone-based post-discharge nursing care in decreasing readmission rate in patients with heart failure</p> <p><i>The Joanna Briggs Institute (JBI) Library</i></p>	<p>To examine the best available evidence to determine the effectiveness of telephone-based post-discharge nursing care of patient with heart failure( HF) and to quantify the effect on all-cause readmission rates</p>	<p>SR Quantitative with Meta-analysis</p> <p>Level 1</p> <p>Telephone-based post discharge and readmission rates</p>	<p>10 RCT. 7 RCT from the US, 3 from Europe. Heart failure patients. No age limit. Settings- all in acute care facilities.</p>	<p>Heterogeneity was analyzed using chi square- 3 months intervention-0.90 (95% CI 0.70-1.16) 6 mons.-0.82 (95% CI .68-.99) 1 yr.-0.67 (95% CI 0.56-0.80)</p>	<p>Moderate to high with no low-quality rated study. 6 studies found that telephone-based post-discharge nursing intervention reduced the hospital readmission rate.</p>	<p>Future studies are needed in Europe and Asian countries growing incidence of HF under different lifestyle and diet pattern. Only published studies Small number of studies</p> <p>Beneficial in my project</p>
<p>Kind et al. (2012)</p> <p>Low-cost transitional care with nurse manager making mostly phone contact with patients cut rehospitalization at a VA hospital.</p> <p><i>Health Affairs</i></p>	<p>To reduce 30-day rehospitalizations and improve care coordination and outcomes among veterans with high-risk conditions discharged to community settings.</p>	<p>Prospective with a baseline comparison</p> <p>Level IV</p>	<p>708 high -risk veterans and cognitively impaired.</p> <p>Majority male, white and older than 75 years.</p> <p>April 1, 2010- March 31, 2012</p> <p>William S. Middleton Memorial Veterans Hospital, in Madison, Wisconsin</p>	<p>C-TraC intervention- experienced lower rates of thirty-day rehospitalization compared to the baseline group (p=0.013)</p> <p>Using multivariate logistic regression models- (odds ratio: 0.55; 95% CI: 0.33, 0.90; P=0.018)</p>	<p>Patients who received the C-TraC protocol experienced one-third fewer rehospitalizations than those in a baseline comparison group, producing an estimated savings of \$1,225 per patient net of programmatic costs</p>	<p>Single VA hosp. Nurse manager was not available on weekend or holiday.- missed qualified veterans Statistical modeling was used.</p> <p>Intervention is beneficial but the subject in the study is questionable.</p>

First author, Year, Title, Journal	Purpose	Research Design, Evidence Level2 & Variables	Sample & Sampling, Setting	Measures & Reliability (if reported)	Results & Analysis Used	Limitations & Usefulness
<p>Heart Failure Society of America [HFSA] et al., 2010</p> <p>Executive Summary: HFSA 2010 Comprehensive</p> <p><i>Journal of Cardiac Failure</i></p>	<p>To provide recommendations for the evaluation and management of patients with acute decompensated heart failure</p> <p>To update and expand the previous 2006 clinical practice guidelines</p>	<p>Guidelines</p> <p>Level I</p>	<p>Patients with acute decompensated heart failure (ADHF)</p>	<p>Major Outcomes Considered :</p> <p>Sensitivity and specificity of diagnostic tests</p> <p>Hospitalization rate</p> <p>Survival rate</p>	<p>Recommended during discharge planning to include schedule follow-up clinic schedule in seven to ten days , follow-up telephone calls and home visits within three days after discharge . Careful monitoring of ADHF patients soon after discharge can prevent or limit the likelihood of readmission</p>	<p>HF patients</p> <p>Beneficial</p>
<p>Lim, Foust, and Van Cleave (2012)</p> <p>Transitional care. In M. Boltz, E. Capezuti, T. Fulmer, &amp; D. Zwicker</p> <p><i>Evidence-based geriatric nursing protocols for best practice</i></p>	<p>To provide a standard of practice protocol to:</p> <p>Assist nurses in assuming a proactive role in transitional care across health care settings</p> <p>Assist nurses in identifying barriers to successful transitions and offering sustainable solutions</p> <p>Increase coordination of care during transitions across health care settings amongst all members of the health care system, including the family and informal caregivers</p>	<p>Evidence-based practice protocol</p> <p>Level I</p>	<p>Adults age 65 and older across health care settings (hospitals, nursing homes, assisted living, homecare )</p>	<p>Patient satisfaction and involvement with care during hospitalization and transitions of care across health care settings</p> <p>Patient feeling of empowerment in making health care decision</p> <p>Rate of rehospitalization and emergency department visits because of primary disease and comorbidities</p> <p>Rate of successful and safe health care transitions</p>	<p>Recommended regular home care visits by the transitional care nurse (TCN), and telephone support for at least two months post discharge. The best practice protocols also suggested continuity of care by timely follow up visits, comprehensive and holistic focus on each patient’s needs, active engagement of patients, family and informal caregiver, multidisciplinary approach, and physician-nurse collaboration</p> <p>To reduce transitional-related medication discrepancies, patients should carry a copy of their recent medication list to share with all their healthcare providers</p>	<p>Adult age 65 and older</p> <p>Useful</p>

First author, Year, Title, Journal	Purpose	Research Design, Evidence Level2 & Variables	Sample & Sampling, Setting	Measures & Reliability (if reported)	Results & Analysis Used	Limitations & Usefulness
<p>Yancy et al. (2013)</p> <p>2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines</p> <p><i>Journal of the American College of Cardiology,</i></p>	<p>To assist clinicians in clinical decision making by describing a range of generally acceptable approaches to the diagnosis, management, and prevention of heart failure (HF)</p> <p>To define practices that meet the needs of most patients in most circumstances</p>	<p>Guidelines</p> <p>Level I</p>	<p>Adults with heart failure (HF)</p>	<p>Major Outcomes</p> <p>Morbidity and mortality due to heart failure (HF)</p> <p>Symptoms of HF</p> <p>Cardiovascular events</p> <p>Risk of HF</p> <p>Risk of death and hospitalization</p> <p>Survival rates</p> <p>Quality of life and sense of well-being</p> <p>Adverse effects</p>	<p>In care coordination and transition, the guidelines recommended to written discharge instructions or educational material given to patient and caregiver at discharge to home, follow-up appointment in seven to fourteen days, and follow up telephone call within three days post hospital discharge</p> <p>During hospital discharge of HF patients, medication reconciliation, consistent documentation, timely transmittal of changes in orders and new diagnostic information to all of the patient's healthcare providers. Multidisciplinary HF disease-management programs for high risk pts.</p>	<p>HF patients</p> <p>Beneficial</p>

Appendix B

Theoretical Framework Diagram

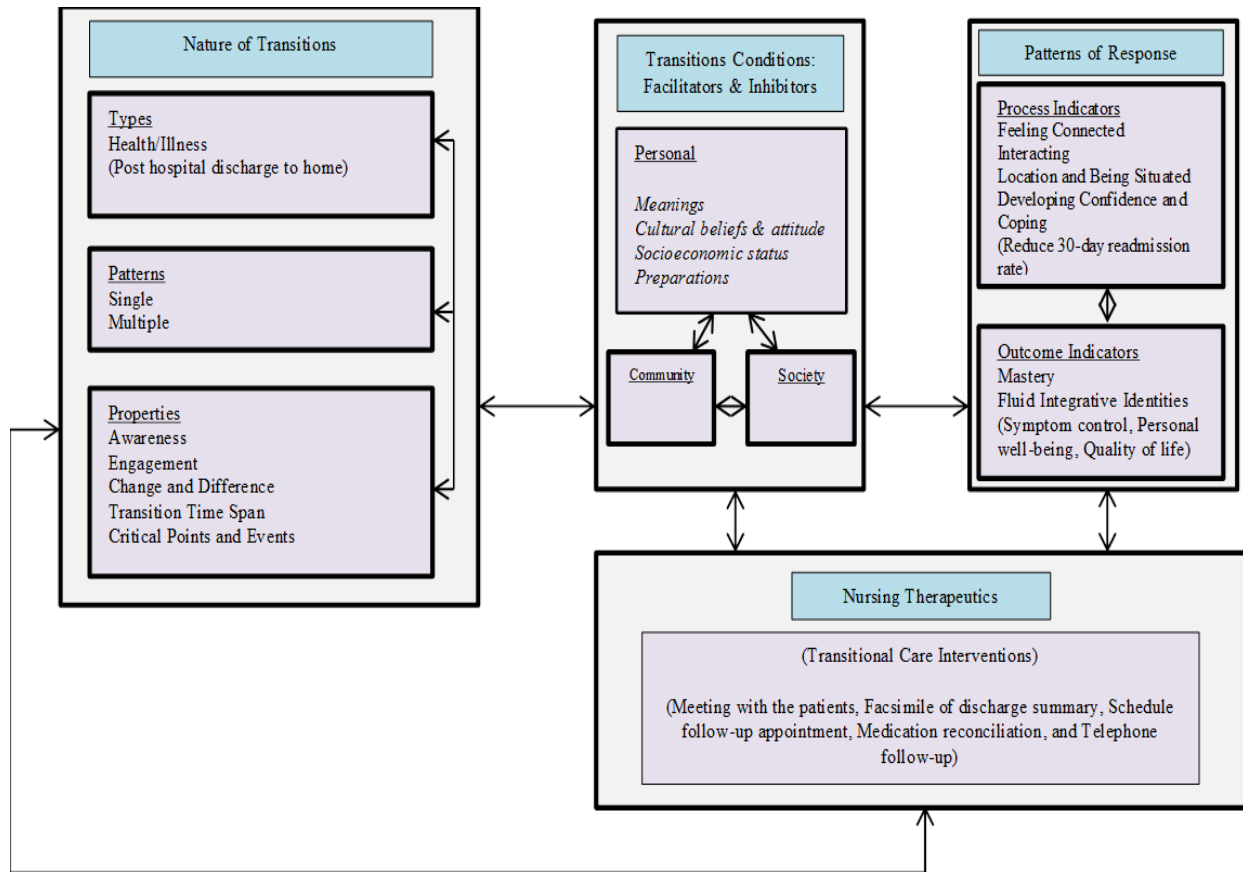


Figure 1. The Modified Transitions Theory. Adapted from “Experiencing transitions: An emerging middle range theory,” by Meleis, A.I., S.M., Im, E.O., Hilfinger Messias, D.A., & Schumacher, K., 2000, *Advances in Nursing Science*, 23(1), p. 16.

Appendix C  
 Figure 2. Logic Model for DNP Diagram

Inputs	Intervention(s)		Outcomes -- Impact		
	Activities	Participation	Short	Medium	Long
<p><b>Evidence, sub-topics</b></p> <p>Increase readmission                      Increase healthcare cost                      Lack of coordination                      Misinformation                      Ineffective transition</p> <p><b>Major Facilitators or Contributors</b></p> <p>APRN                      Medical Director                      Administrator                      Cardiologist                      Patients                      Caregivers</p> <p><b>Major Barriers or Challenges</b></p> <p>EHR-missing patients info</p> <p>APRN overwhelming patient's loads, lack of time, lack of knowledge of the intervention, and resistance to change</p> <p>Patient's socioeconomic status- difficulty in keeping up the intervention.</p>	<p><b>The EBP intervention which is supported by the evidence in the Input column</b></p> <p>Transitional Care Intervention</p> <p><b>Major steps of the intervention</b></p> <p>Meet with the patient/ participant (discuss nature, duration, severity of illness, review general health behaviors and skills, availability of social support)</p> <p>Facsimile of discharge summary w/in 48 hours</p> <p>Schedule follow up appointment with PCP/Cardiologist w/in 7-10 days of discharge</p> <p>Telephone follow up w/in 48 hours (review meds, refills, med changes, labs, v/s, s/s of rejection and infection)</p>	<p><b>The participants (subjects)</b></p> <p>Cardiac Transplant Patients                      18 years and older                      English speaking</p> <p><b>Site</b>                      Outpatient Medical Center- NY</p> <p><b>Time Frame</b>                      Summer 2015                      IRB-approval</p> <p>Fall 2015                      Implements intervention                      Sept. 1 –Dec.1, 2015</p> <p>Spring 2016                      Evaluation/results analysis</p> <p><b>Consent Needed or other</b>                      Obtain Consent</p> <p><b>Person(s) collecting data</b>                      APRN</p> <p><b>Others directly involved.</b>                      Statistician</p>	<p><b>(Completed as a student).</b></p> <p>Reduce 30-day all cause hospital readmission rate</p> <p><b>Outcome(s) to be measured with reliable measurement tool(s)</b></p> <p>Baseline usual group and intervention group                      30-day readmission rate</p> <p><b>Statistical analysis to be used.</b></p> <p>Chi Square                      Fisher's Exact Test                      Independent T-test</p>	<p><b>Outcomes to be measured (past DNP student time).</b></p> <p>Reduce 6 and 12 months all cause hospital readmission rate</p>	<p><b>Outcomes that are potentials (past DNP student)</b></p> <p>Reduce readmission rate (to include HF patients)</p> <p>Effectiveness of NP-led transitional care intervention</p> <p>Decrease healthcare cost</p> <p>Improvement in QOL, satisfaction, self-efficacy and self-management skills and abilities</p> <p>Provide a tool to the department to prevent readmission rate</p> <p>Incorporate TCI to the department policy and procedure</p>

Adapted from Logic-Model Worksheet content revisions by Dr. Lyla Lindholm  
 (Rev. 7/09, 1/2015, [http://www.uwex.edu/ces/lmcourse/interface/coop\\_M1\\_Overview.htm](http://www.uwex.edu/ces/lmcourse/interface/coop_M1_Overview.htm))

Appendix D

Cost Table

Table 1

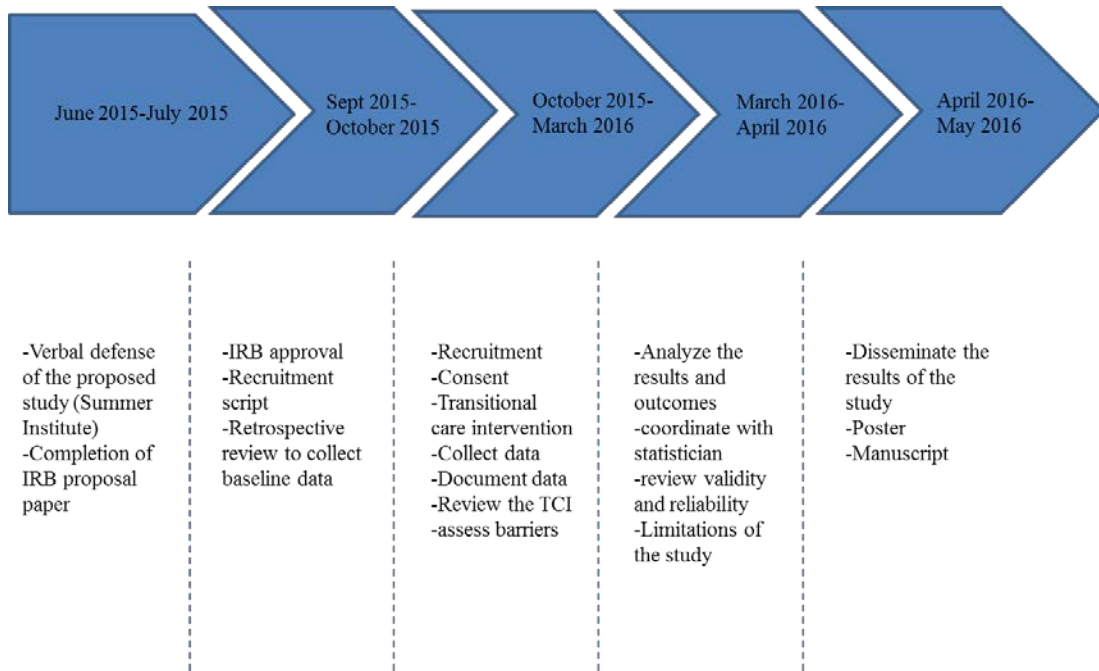
*Cost Savings Analysis of the Transitional Care Intervention (TCI)*

<b>Cost Analysis</b>	<b>Amount</b>
<b>Cost of Readmission (Based on Rizzo data- \$12,000 per readmission x 6 readmission in 3 months)</b>	\$72,000
<b>Cost of the TCI project for 3 months</b>	\$32,000
<b>Direct cost</b>	
<b>APRN wages and benefits (\$58.33 x 480 hours/3 months)- \$28,000</b>	
<b>Indirect cost</b>	
<b>Office supplies/postages- \$1200</b>	
<b>Local and long distance calls, Internet-\$800</b>	
<b>Fax and Copier rental (small size)-\$800</b>	
<b>One desktop computer-\$1200</b>	
<b>Predicted total savings of the pilot project in 3 months</b>	\$40,000

Appendix E

Implementing Transitional Care Intervention Timeline

Figure 3: Transitional Care Intervention Timeline



Appendix F

Transitional Care Intervention Diagram



Figure 4. Transitional Care Intervention Diagram



Appendix G

Approval Letters- IAA, IRB, & UMKC

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Message IAA P9551.pdf

Version Date: 12/2007

**Institutional Review Board (IRB)/Independent Ethics Committee (IEC)  
Authorization Agreement**

Name of Institution or Organization Providing IRB Review (Institution/Organization A):  
Columbia University Medical Center (CUMC IRB)  
IRB Registration #: IRB00008612  
Federalwide Assurance (FWA) #: 00602636

Name of Institution Relying on the Designated IRB (Institution B): University of Missouri -  
Kansas City (UMKC)  
FWA #: 00005427

The Officials signing below agree that UMKC may rely on the designated IRB for review and continuing oversight of its human subjects research described below:

This agreement applies to all human subjects research covered by Institution B's FWA.

This agreement is limited to the following specific protocol(s):

Protocol Number: CUMC IRB#-AAAP9551  
Name of Research Project: Transitional Care Intervention to Reduce 30-day Readmission Rate  
Name of Principal Investigator: Paul Schulze  
Sponsor or Funding Agency: N/A

The review performed by the designated IRB will meet the human subject protection requirements of Institution B's OHRP-approved FWA. The IRB at Institution/Organization A will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB's determinations and with the Terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

Signature of Signatory Official (Institution/Organization A): \_\_\_\_\_ Date: 11/26/15

Print Full Name: Steven Shea, M.D. Institutional Title: Senior Vice Dean  
Columbia University Medical Center  
630 W. 168<sup>th</sup> Street, 2<sup>nd</sup> Floor  
New York, NY 10032

Signature of Signatory Official (Institution B): \_\_\_\_\_ Date: 9/9/2015

Print Full Name: Lawrence A. Dreyfus Institutional Title: Vice Chancellor  
Office of Research Services  
University of Missouri - Kansas City  
5211 Rockhill Rd, Kansas City, MO 64110

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August 10, 2015

Paul Schulze  
MED Cardiology - 751830X  
Division of Cardiology  
622 W 168th Street  
PH 10-203



COLUMBIA UNIVERSITY  
MEDICAL CENTER

Institutional Review Board  
154 Haven Avenue, 1st Floor  
New York, NY 10032  
212.305.5883 Tel  
212.305.1316 Fax



Protocol Number: IRB-AAAP9551  
Title: Transitional Care Intervention to Reduce 30-day Readmission Rate  
Approval Date: 07/30/2015 Expiration Date: 07/29/2016

Dear Dr. Schulze,

On July 30, 2015, the above-mentioned study was reviewed and approved by the Chair or Designee of the Columbia University Medical Center Institutional Review Board Exp. It met the regulatory guidelines for expedited review, category #5 and 7. You may now begin human research for this study.

Important - Please submit a modification to address the following:

- 1) Per the Privacy Office, the 25 subjects included in your retrospective analysis are selected from 100 charts reviews. Please update all sections of the protocol, including the Subjects page, to reflect that 100 patient charts will be accessed for this component.
- 2) It is noted that Paul Schulze's CITI Human Subjects Protection (HSP) training was completed on 6/27/2011 (now expired) and HSP recertification training is required. Please ensure that the CITI HSP re-certification training is complete as soon as possible. The required research exam can be accessed through the RASCAL website, [www.rascal.columbia.edu](http://www.rascal.columbia.edu), Training Center, HSP exam TC0087.
- 3) Please update the Procedures page to reflect "Yes" for the field asking if Survey/Interview/Questionnaires are utilized in your research. The questions asked during the telephone follow-up process is considered a questionnaire.
- 4) Please update the last field found in the Procedures page to include additional details about the procedures conducted in the prospective component (e.g. follow-up telephone survey etc.)
- 5) Please update the Recruitment and Consent page to select the following designation for your retrospective component and complete the subsequently generated fields:  
[ ] A waiver of some or all elements of informed consent (45 CFR 46.116) is requested.
- 6) Please make the following changes to the Informed Consent Form:
  - (a) Please update the Introduction section to refer to this project as a "research study".
  - (b) Please correct grammatical errors found in the "What will you do if you choose to be in this study?" section (e.g. faxing instead of fax, scheduling instead of schedule).
  - (c) Please update the Benefits section to explain that subjects will likely receive no direct benefit through participation.
  - (d) Please update the "Who may use, disclose, or receive your health information?" section to list the following entities:
    - The Office of Human Research Protections (OHRP)
    - The Columbia University Institutional Review Board

During the approval period, all subjects enrolled not only must provide voluntary informed consent to participate in the study, but also must sign a copy of the appropriate stamped consent document(s). A copy of the consent document(s) must be given to the subjects for their record. However, the requirement to obtain informed consent for the retrospective component has been waived by the IRB in accordance with 45 C.F.R. § 46.116(d).

The following study-related materials were approved:

- Informed Consent Form, attached 07/23/2015
- Intervention checklist and Telephone call follow up script, attached 07/23/2015
- HIPAA Form(s): HIP-AAAM4204 and HIP-AAAM4205

Any proposed changes in the protocol must be immediately submitted to the IRB for review and approval prior to implementation, unless such a change is necessary to avoid immediate harm to the participants. Additionally, any unanticipated problems that involve risks to subjects must be reported to the IRB in accordance with the CUMC Unanticipated Problems: Reporting to the IRB of Unanticipated Problems Involving Risks policy. All submissions for modifications and unanticipated problems must be submitted through RASCAL.


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Institutional Review Board  
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AAAP9551  
Page 2 of 2  
7/30/15 Approval Letter

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212.305.5883 Tel  
212.305.1316 Fax

Renewal applications should be submitted 60 days before the expiration date of this study through RASCAL. Failure to obtain renewal of your study prior to the expiration date will require discontinuance of all research activities for this study, including data analysis. You must inform the IRB when your study has been completed via a Closure report in Rascal.


If you have any questions regarding this approval, please call Rafael Santos at (212) 305-9008.

Columbia University appreciates your commitment towards the ethical conduct of human research.

Sincerely,

Rafael Santos, CIP  
Assistant Manager, IRB 5-Expedited

Electronically signed by: Santos, Rafael

Columbia University IRB  
Approved for  
use until: 07/29/2016 


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September 22, 2015

Paul Schulze  
MED Cardiology - 751830X  
Division of Cardiology  
622 W 168th Street  
PH 10-203



COLUMBIA UNIVERSITY  
MEDICAL CENTER

Institutional Review Board  
154 Haven Avenue, 1st Floor  
New York, NY 10032  
212.305.5883 Tel  
212.305.1316 Fax



Protocol Number: IRB-AAAP9551  
Title: Transitional Care Intervention to Reduce 30-day Readmission Rate  
Approval Date: 09/16/2015 Expiration Date: 07/29/2016

Dear Dr. Schulze,

On September 16, 2015, a modification to the above-mentioned protocol was reviewed and approved under an expedited review procedure by the Chair or Designee of the Columbia University Medical Center Institutional Review Board Exp. You may now implement the following.

**Modification:**

- Incorporation of previous IRB requests
- Request to cover the University of Missouri – Kansas City’s involvement in this research
- Target subject enrollment revised to 100

**Important Reminders:** Please note that the University of Missouri at Kansas City is not authorized for involvement in this research until the submitted IRB Authorization Agreement is fully executed.

During the approval period, all subjects enrolled not only must provide voluntary informed consent to participate in the study, but also must sign a copy of the appropriate stamped consent document(s). A copy of the consent document(s) must be given to the subjects for their record for prospective component. However, the requirement to obtain informed consent from the subjects for the retrospective component has been waived by the IRB in accordance with 45 C.F.R. § 46.116(d).

The following study-related materials were approved:

- IRB Updated Informed Consent, attached 8/27/2015

Any additional changes proposed for this protocol must be immediately submitted to the IRB for review and approval prior to implementation, unless such a change is necessary to avoid immediate harm to the participants. Additionally, any unanticipated problems that involve risks to subjects must be reported to the IRB in accordance with the CUMC IRB Unanticipated Problems: Reporting to the IRB of Unanticipated Problems Involving Risks policy. All submissions for modifications and reports of unanticipated problems must be submitted through RASCAL.

Renewal applications should be submitted 60 days before the expiration date of this study through RASCAL. Failure to obtain renewal of your study prior to the expiration date will require discontinuance of all research activities for this study, including data analysis. You must inform the IRB when your study has been completed via a Closure report in Rascal.


If you have any questions regarding this approval, please call Rafael Santos at (212) 305-9008.

Columbia University appreciates your commitment towards the ethical conduct of human research.

Sincerely,

Rafael Santos, CIP  
HRPO Manager, IRB 5-Expedited

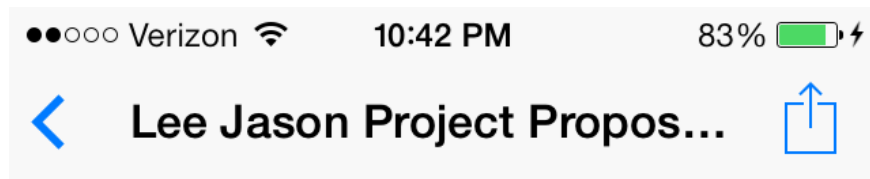
Electronically signed by: Santos, Rafael



Columbia University IRB  
Approved for  
use until: 07/29/2016

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July 16, 2015

Dr. Mary O'Connor  
Members of the Social Science Institutional Review Board  
University of Missouri-Kansas City  
Kansas City, MO 64108

Dr. O'Connor;

This letter serves to provide documentation regarding Jason Lee's Doctor of Nursing Practice (DNP) project proposal. Mr. Lee obtained approval for his project proposal, Transitional Care Intervention to Reduce 30-day Readmission Rate in Cardiac Transplant Patients, from the School of Nursing DNP faculty committee on July 15, 2015.

If I can provide any further information, please feel free to contact me

Sincerely,

A handwritten signature in cursive script that reads "Susan J. Kimble".

Susan J. Kimble, DNP, RN, ANP-BC  
Clinical Associate Professor  
MSN and DNP Programs Director  
UMKC School of Nursing and Health Studies  
kimbles@umkc.edu  
[816-235-5962](tel:816-235-5962)

Appendix H

Approved Informed Consent Form

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**Columbia University Medical Center  
Informed Consent Form**

**PROTOCOL TITLE:** Transitional Care Intervention to reduce 30-day Readmission Rate  
**PRINCIPAL INVESTIGATORS:** Paul Christian Schulze M.D., Ph.D.  
**STUDENT INVESTIGATOR:** Jason Lee NP  
**DEPARTMENT:** Columbia University Medical Center- Adult Cardiac Transplant  
**IRB Number:** AAAP9551

**Introduction**  
You are being asked to take part in a research study. The aim of this consent form is to give you the information you will need to help you decide whether or not to be in the study. Please read the form carefully. You may ask questions about the purpose of the study, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the study or this form that is not clear. When all your questions have been answered, you can decide if you want to be in the study or not. This process is called "informed consent".

**What is the reason for doing this study?**  
The purpose of the quasi-experimental pilot project is to examine the effectiveness of transitional care interventions during post hospitalization on 30-day readmission rate in cardiac transplant patients.  
  
We expect to enroll 30 participants with principal diagnosis of cardiac transplant at our medical center.  
  
Your length of participation will be for 30 days post hospital discharge.

**What will you do if you choose to be in this study?**  
If you consent to participate, you will receive the transitional care intervention post hospital discharge from a nurse practitioner (student investigator). The transitional care intervention will include meeting with you (the participants), faxing a discharge summary to your primary care provider (PCP) and transplant cardiologist, scheduling a follow up appointment with your PCP and transplant cardiologist, and telephone call follow-up. The telephone follow up will include assessing your (participants) overall health status, review signs and symptoms of cardiac rejection and infection, review of home vital signs, review of medication's adherence, and side effects. You will receive two follow up telephone calls a week for 4 weeks.  
  
Each participant in the proposed project will receive the transitional care intervention for 30 days post hospital discharge. The 30-day readmission rate will be the outcome measures.


**What are some of the possible risks and discomforts?**  
Your participation does not involve any physical risk to you.  
As with any research registry, there is the potential risk of loss of confidentiality.


**What are the Possible Benefits for Me or Others?**  
You will not likely have any direct benefit from being in this study. Taking part in this study may help clinicians to better understand if transitional care intervention can reduce 30-day readmission rate. This will help improve the quality of care and reduce healthcare cost.


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IRB-AAAP9551  
IRB Approval Date: 09/18/2015  
for use until: 07/29/2018

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 IRB-AAAP901  
 IRB Approval Date: 09/16/2015  
 for use until: 07/29/2016

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**What other procedures or courses of intervention might be available to me?**  
 You do not have to take part in the transitional care intervention. Instead of being in this study, you can choose not to participate. You will receive usual discharge care.

**Are there any financial costs to being in this study?**  
 There will be no costs to you for being in this study.

**Will I receive payment for participation in this study?**  
 You will not be paid for your participation in this study.

**What are my rights as a study subject?**  
 You are free to choose to stop being in the study at any time.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you. Specifically, choosing not to be in this study will not negatively affect your right to any present or future medical treatment.

Any new findings developed during the course of this study that may affect your willingness to continue in this study will be shared with you.

Your participation in this study may be stopped by the student investigator without your consent if:

- The principal and student investigators believe that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- You do not follow instructions from the student investigator.


The Institutional Review Board (IRB) may also end the study at any time.

**What about my confidentiality and privacy rights?**  
 We are committed to respecting your privacy and to keeping your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information, including health information in your medical records and information that can identify you. For example, personal health information may include your name, medical record number, and phone number. Your health information that we may collect and use for this study includes:

- All information in a medical record
- Hospital discharge summary
- Medical history including physical exams, labs, and other test results
- Records about medication or drugs

Columbia University Medical Center cardiologists and nurse coordinators will notify the student investigator on patient's interest to participate in the study. The student investigator will obtain informed consent for this study. All other study-related procedures are performed by the principal and student investigators.

We will maintain appropriate security measures for the subject identifiers, including: (a) storing physical files in a locked cabinet to which only study staff can access with a key or combination lock; and/or (b) maintaining a secure database to which only the principal and student investigators can access with a password. All data will be coded to protect patient information.


 Columbia University IRB  
 IRB-AAAP901  
 IRB Approval Date: 09/16/2015  
 for use until: 07/29/2016

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**Who may use, disclose, or receive your health information?**  
 The following person(s), class(es) of persons, and/or organizations may use, disclose, or receive your health information:

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Records about medication or drugs  
Columbia University Medical Center cardiologists and nurse coordinators will notify the student investigator on patient's interest to participate in the study. The student investigator will obtain informed consent for this study. All other study-related procedures are performed by the principal and student investigators.

We will maintain appropriate security measures for the subject identifiers, including: (a) storing physical files in a locked cabinet to which only study staff can access with a key or combination lock; and/or (b) maintaining a secure database to which only the principal and student investigators can access with a password. All data will be coded to protect patient information.

Columbia University IRB  
IRB-AAA9201  
IRB Approval Date: 05/16/2015  
for use until: 07/29/2016

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**Who may use, disclose, or receive your health information?**

The following person(s), class(es) of persons, and/or organizations may use, disclose, or receive your health information:

- The principal and student investigators, your primary care provider, and transplant cardiologist
- The office of Human Research Protection (OHRP)
- The Columbia University Institutional Review Board

Any information derived from this research project that personally identifies you will not be voluntarily released or disclosed without your separate consent, except as specifically required by law.

**If I have questions or concerns about this study, whom can I call?**

If you have any questions or concerns about the study you may contact the Principal Investigator, Dr. Paul Christian Schulze at 212-305-7912 and student investigator, Jason Lee NP at 212-305-9640.

If you have any questions about your rights as a subject you may contact:

Institutional Review Board Columbia University Medical Center/New York Presbyterian Hospital  
154 Haven Ave, 1st Floor New York, New York 10032  
Telephone: 212-305-5883  
Email: irboffice@columbia.edu

An Institutional Review Board is a committee organized to protect the rights and welfare of human subjects involved in research.

**Please note that:** You do not have to sign this consent form. If you choose not to, it will not affect your treatment by health care providers. However, you will not be allowed to take part in this research study.

**Consent Summary:**

I have read this consent form and the research study has been explained to me. I have been given time to ask questions, and have been told whom to contact if I have more questions. I agree to be in the research study described above. A copy of the consent form will be provided to me after I sign it.

\_\_\_\_\_  
Subject's Name (printed) and Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name (printed) and Signature of Person Obtaining Consent

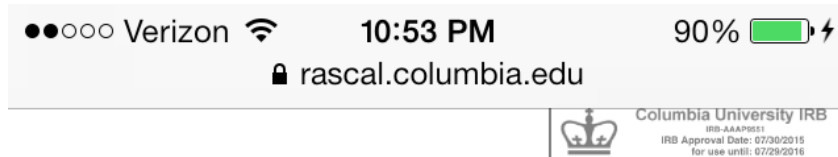
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Date

Columbia University IRB  
IRB-AAA9201  
IRB Approval Date: 05/16/2015  
for use until: 07/29/2016



Appendix I
Intervention Checklist
Transitional Care Intervention (TCI) for 30 Days Post Hospital Discharge

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Intervention Checklist
Transitional Care Intervention (TCI) for 30 Days Post Hospital Discharge
Protocol: AAAP9551
Participant Code Number:
Start Date of TCI:
End Date of TCI:
I. Meeting with the Participant ..... Yes/ No
II. Facsimile of Discharge Summary ..... Yes/No
III. Follow up Appointment ..... Yes/No
IV. Telephone call Follow-up ..... Yes/No
Dates
WEEK 1:
WEEK 2:
WEEK 3:
WEEK 4:
Columbia University IRB
IRB Approval Date: 07/29/2015
for case ID#: 07/29/2015
2



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### Follow up Telephone call Script

**This form will reinforce the information provided to the patient at discharge. The participant's discharge summary should be available to the nurse practitioner (student investigator) at the time of this call.**

#### Introduction

**CALLER:** Hello Mr./Ms. \_\_\_\_\_. I am Jason Lee, a nurse practitioner from Columbia University Medical Center- cardiac transplant department. You may remember that when you left, we had discussed that you will receive a telephone call from me. I am hoping to talk to you about your medical issues, see how you are doing, and see if there is anything I can do to help you. Do you mind if I ask you a few questions so I can see if there is anything I can help you with?

Is this a good time to talk? It will probably take about 10 to 15 minutes, depending on the number of medicines you are taking.

If yes, continue.

If no, **CALLER:** Is there a better time that I can call you back?

#### Assessing participants overall health status

**CALLER:** Since you left the hospital, do you feel your main problem, [diagnosis], has improved, worsened, or not changed? What does your family or caregiver think?

If improved or no change, continue below.

If primary condition has worsened,

**CALLER:** I'm sorry to hear that. How has it gotten worse? Have you spoken to or seen any doctors or nurse practitioner about this since you left the hospital?

If yes, **CALLER:** Who have you spoken with/seen? And what did they suggest you to do? Have you done that?

Using clinical judgment, use this conversation to determine if further recommendations, teaching, or interventions are necessary.

#### Review of home vital signs, and signs and symptoms of cardiac rejection and infection

**CALLER:** What did the medical team at the hospital tell you to watch out for to make sure you are okay?

Review specific symptoms to watch out for/things to do for this diagnosis (e.g., check blood sugar, check blood pressure).

Review participant understands of sign and symptoms of rejection and infection

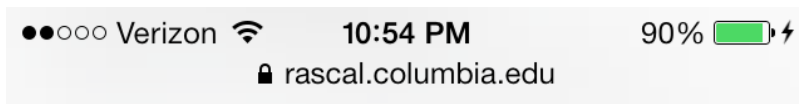
Signs and symptoms of rejection include shortness of breath, difficulty breathing on exertion, sudden onset of difficulty breathing at night while asleep, swollen feet, hands, and face, fatigue, chest pain, palpitation, dizziness, syncope, and headache.

Signs and symptoms of infection include fever, chills, nausea, vomiting, diarrhea, abdominal pain, cough, difficulty in urination, and leg swelling and pain.

#### Review of medication's adherence, and side effects. Medication reconciliation

**CALLER:** Can you bring all of your medicines to the phone, please? We will review them during this call. Bring both prescription medicines and over-the-counter medicines, the ones you





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can buy at a drugstore without a prescription. Also, bring any supplements or traditional medicines, such as herbs, you are taking. Finally, could you also please bring to the phone the care plan that we gave you before you left the hospital?

**CALLER:** Do you have all of your medicines in front of you now?

**CALLER:** I'm going to ask you a few questions about each one of your medicines to see if there is anything I can help you with. We will go through your medicines one by one.

First of all, I want to make sure that the medicines you were given were the right ones. Then we'll discuss how often you've been able to take them and any problems or questions you might have about any of them.

Choose one of your medicines to start with.

What is the name of this medicine? The name of it should be on the label. If the patient is using a generic, check that he or she understands that the brand and generic names are two names for the same medicine.

At what times during the day do you take this medicine?

How much do you take each time?

If the participant answers in terms of how many pills, lozenges, suppositories, etc. What is the strength of the medicine? It should say a number and a unit such as mg or mcg.

How do you take this medicine?

If there are special instructions (e.g., take with food), probe as to whether the participant knows the instructions and whether he or she is taking the medicine as instructed.

What do you take this medicine for?

Have you had any concerns or problems taking this medicine? Has anything gotten in the way of your being able to take it? Have you ever missed taking this medicine when you were supposed to? Why?

Do you think you are experiencing any side effects from the medicine?

If yes, could you please describe these side effects?

Are you taking any other medicines? Repeat list of questions for each medicine.

After participant has described all medicines, ask: Are you taking any additional medicines that you haven't already told me about, including other prescription medicines, over-the-counter medicines, that is, medicines you can get without a prescription, or herbal medicines, vitamins, or supplements?

If the participant has been prescribed medicines that the participant hasn't mentioned, ask whether he or she is taking that medicine.

If yes, go through the list of medicine questions.

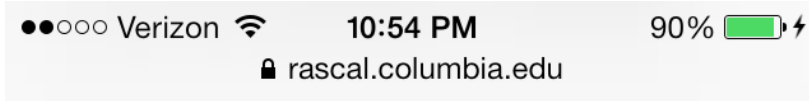
If not, probe as to why not. If participant is unaware of the medicine, make a note to check with discharge physician as to whether participant is supposed to be taking it, whether a prescription was issued, etc.

**Reiterate the contact number to call for urgent and emergency issues and medication refills as needed.**

**CALLER:** Before we hang up, I want to make sure that if a medical problem arises, you know what to do. If you're having an emergency, for example chest pain, trouble breathing, what would you do?

If participant does not say, "Call 911," explains the need to get an ambulance so he or she can see a doctor right away, and confirm participant understanding.





**CALLER:** And what about if you develop leg swelling, increasing shortness of breath, low and high blood pressure, fever, cough in the evening? What would you do then? Check if the participant knows how to reach the doctor after hours. If not, instruct participant to call 212-305-7600. Confirm understanding.

**CALLER:** And what about if you are having a medical problem that is not an emergency, back pain, poor appetite, sore throat, difficulty sleeping and want to be seen by your doctor before your next scheduled appointment, what would you do?

If participant does not know, instruct: You can call your doctor's office directly and ask for an earlier appointment. Sometimes your doctor is very busy, so if you are having difficulty obtaining an appointment, ask if you can be seen by someone else in the office, such as a nurse practitioner, or physician's assistant. Confirm understanding.

**CALLER:** Just to make sure we're on the same page, can you tell me what you'd do if [create non emergent scenario]?

If patient answers incorrectly, ask: Do you have your doctor's phone number handy? It should be on the discharge summary on the appointments page. If participant can't tell you the number, say, let me give you the phone number for your primary care doctor just in case. Do you have a pen and paper to write this down? Do you need me to mail or email you another copy of your discharge summary?

Instruct to call 212-305-9296 for assistance with medication refills.

Notes

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Adapted from Agency for Healthcare Research and Quality [AHRQ]. (2013, March). *Postdischarge Followup Phone Call Script: Re-Engineered Discharge (RED) Toolkit*. from <http://www.ahrq.gov/professionals/systems/hospital/red/toolkit/postdischarge-phone.html>



Appendix J

Data Collection Template

Table 2.

*Demographics and Characteristics of Participants*

Comparison of Demographics and Characteristics of Participants of Intervention and Usual Groups					
Characteristic	Total Populations (n=43)	Intervention Group (n=24)	Usual Group (n=19)	Statistical Comparison p-value	
Age In mean years (+/-SD)		55.5 (14.50)	56.2 (12.44)	0.858	
<b>Age groups</b>				0.985	
18-40	7 (16.3)	4 (16.7)	3 (15.8)		
41-64	23 (53.5)	13 (54.2)	10 (52.6)		
65 and older	13 (30.2)	7 (29.1)	6 (31.6)		
<b>Sex</b>				0.76	
Male	33 (76.7)	18 (75)	15 (78.9)		
Female	10 (23.3)	6 (25)	4 (21.1)		
<b>Race</b>				0.594	
White	18 (41.9)	11 (45.8)	7 (36.8)		
Black or African American	13 (30.2)	6 (25)	7 (36.8)		
Asian or Asian American	5 (11.6)	2 (8.3)	3 (15.8)		
Hispanic or Latino	7 (16.3)	5 (20.8)	2 (10.5)		
<b>Marital status</b>				0.974	
Married	26 (60.5)	14 (58.3)	12 (63.1)		
Divorced	3 (7.0)	2 (8.3)	1 (5.3)		
Widowed	5 (11.6)	3 (12.5)	2 (10.5)		
Single	9 (20.9)	5 (20.8)	4 (21.1)		
<b>Highest education level</b>				0.22	
< Highschool (< 12 grade)	16 (37.2)	7 (29.2)	9 (47.4)		
>Highschool (> 12 grade)	27 (62.8)	17 (70.8)	10 (52.6)		
<b>Income</b>				0.248	
<10,000	7 (16.3)	2 (8.3)	5 (26.3)		
10,000-19,999	16 (37.2)	9 (37.5)	7 (36.8)		
>20,000	20 (46.5)	13 (54.2)	7 (36.8)		
<b>Primary payer</b>				0.508	
Medicare	25 (58.1)	13 (54.2)	12 (63.1)		
Medicaid	5 (11.6)	4 (16.7)	1 (5.3)		
All Other	13 (30.2)	7 (29.1)	6 (31.6)		
<b>Years of cardiac transplant</b>				0.57	
< 1 year	8 (18.6)	5 (20.8)	3 (15.8)		
1-5 years	21 (48.8)	10 (41.6)	11 (57.9)		
> 6 years	14 (32.6)	9 (37.5)	5 (26.3)		
<b>Admitting diagnosis</b>				0.184	
Rejection	17 (39.5)	8 (33.3)	9 (47.4)		
Infection	20 (46.5)	14 (58.3)	6 (31.6)		
Others/ Surgery	6 (13.9)	2 (8.3)	4 (21.0)		
<b>Co-morbidities</b>					
Hypertension	32 (74.4)	23 (95.8)	9 (47.4)	0.001	
Diabetes Mellitus (all types)	31 (72.1)	16 (66.7)	15 (78.9)	0.373	
Hyperlipidemia	34 (79.1)	20 (83.3)	14 (73.7)	0.475	
Coronary Allograft Vasculopathy	8 (18.6)	6 (25.0)	2 (10.5)	0.27	
Renal Failure	8 (18.6)	5 (20.8)	3 (15.8)	1	
Stroke	2 (4.7)	1 (4.2)	1 (5.3)	1	
Malignancy (all types)	3 (7.0)	2 (8.3)	1 (5.3)	1	
Chi-Square or Fisher's Exact Test for categorical variables and t-test for continuous variables.					

## Appendix K

## Statistical Analysis Template

Table 3.

*Intervention and Usual Group Cross Tabulation: 30-day Readmission*

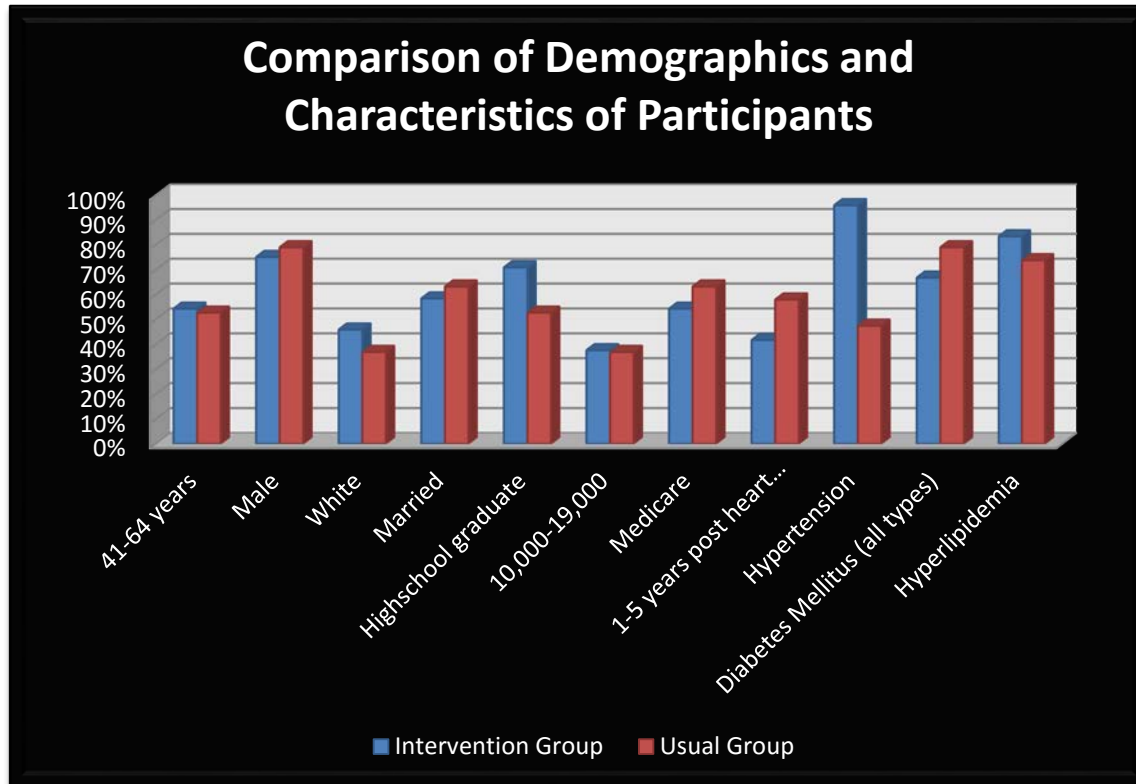
<b>Intervention and Usual Group Cross Tabulation: 30-day Readmission</b>			
	Yes (30-day readmission)	No (30-day Readmission)	<i>Marginal Row Totals</i>
Intervention care group	2	22	24
Usual care group	7	12	19
<i>Marginal Column Totals</i>	9	34	43 (Grand Total)

*Note:* The chi-square statistic is 5.208. The  $p$ -value is 0.02.

The Fisher's Exact test statistic value is  $p=0.03$ .

Appendix L

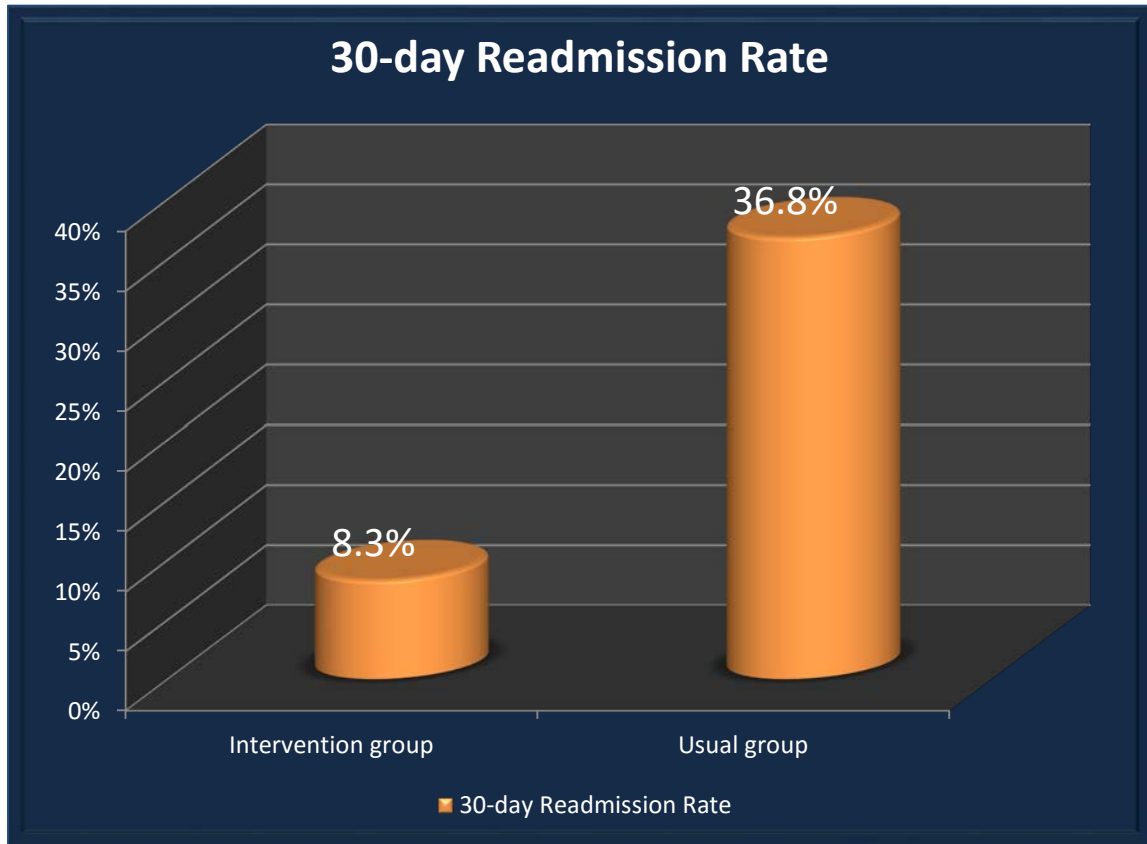
Figure 5. Comparison of Demographics and Characteristics of Participants



Note: Except for hypertension ( $p=0.001$ ), all other characteristics were not statistically different between the groups ( $p>0.18$ ).

## Appendix M

Figure 6. 30-day Readmission Rate of Intervention and usual group



*Note:* TCI revealed statistically significant improvement in the 30-day readmission rate ( $p=0.03$ , Fisher's Exact test).