Implementation of a Patient Navigator Program to reduce 30-day Heart Failure Readmission Rates

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March 4, 2022

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Abstract

Purpose*:* Heart failure (HF) is one of the leading causes of hospital readmission. Hospitals and other health facilities have implemented the Patient Navigator Program (PNP) to help reduce a 30-day heart failure readmission. The purpose of the study was to implement an evidence-based practice PNP in an acute care facility in Mississippi to reduce 30-day heart failure readmissions in six weeks.

Methods: In this study, a comparison of the heart failure readmission rates prior to the implementation of the PNP and the heart failure readmission rates six weeks after the implementation of the PNP was conducted. The PNP was composed of one principal investigator, two nurse navigators, and one pharmacist that provided six evidence-based practice interventions to heart failure patients who met inclusion/exclusion criteria. The patients were followed from admission to six weeks after discharge and a satisfaction survey was also administered.

Results*:* The implementation of the PNP had a 4.77% reduction in heart failure readmission rates at the acute care facility in Mississippi. The heart failure readmission rates decreased within the facility and a five-question Patient Satisfaction Survey was used to measure the performance of the program.

Discussion: Evidence-based practice research has shown that PNPs have been effective in reducing heart failure readmission rates and this study showed similar results and had had a positive impact on the facility's readmission rate. The PNP must be promoted so that facilities become aware of its development and the benefits the program has to offer for heart failure patients and the facility.

Keywords: heart failure, readmission rate, patient navigator program, hospital

Implementation of a Patient Navigator Program to reduce 30-day Heart Failure Readmission Rates

Heart failure is the sixth most expensive condition treated in US hospitals at $10.2 billion with readmissions accounting for $2.7 billion in 2013 (Zohrabian, 2018). Due to the increase in hospital readmissions with heart failure patients, researchers, clinicians, and various stakeholders are focusing on reducing hospital readmissions and improving hospital performance. As heart failure readmission rates continue to rise, it gaining focus on increasing the quality of care and implementing inpatient interventions to prevent or reduce readmissions (Ziaeian & Fonarow, 2016). The reduction of heart failure readmissions can be beneficial by reducing health care costs, improving patient outcomes, and working to avoid complications related to hospital stays such as hospital-acquired infections, falls, and wounds. The purpose of this DNP scholarly project was to implement a Patient Navigator Program at an acute care facility in Mississippi to reduce the 30-day heart failure readmission rate and improve hospital performance.

Background

Heart failure continues to be a healthcare strain and one of the leading causes of hospital readmissions. Currently, in the United States, thirty-day readmission rates for heart failure have been reported to be around 23% (Nair et al., 2020). Due to the increase in hospital readmissions with heart failure patients, researchers, clinicians, and various stakeholders are focusing on reducing hospital readmissions and improving hospital performance. The facility where the project was conducted has targeted reducing their heart failure readmission rates. Some interventions that they have used to potentially prevent a heart failure readmission include a readmission checklist, discharge telephone follow-up, discharge checklist, heart failure education, and several other strategies. Readmission checklists helped to identify gaps that may

have occurred on admission, discharge, or post-discharge that caused readmission. Discharge telephone follow-up helped to ensure the patient's understanding of and adherence to discharge orders. Also, discharge telephone follow-up allowed patients to ask questions and report changes in their condition early. A discharge checklist was used to ensure that heart failure patients' discharge needs are met which include education, follow-up appointments, medications, etc. Heart failure education helped to teach patients about diet, activity, medications, weight monitoring, symptoms, and when to call your healthcare provider.

Current Situation

In 2020, there was a total of 265 heart failure cases at this facility with an average readmission rate of 19.25%. As of April 2021, there have been 132 heart failure cases with a 15.15% readmission rate. The facility is the only 315-bed acute care hospital located in this rural area of northeast Mississippi. This facility has served the residents of northeast Mississippi and west Alabama for over 45 years and continues to strive to meet the needs of the residents of this community by providing high-quality health care services, reducing healthcare costs, and emphasizing patient safety. Although the facility is below the national heart failure readmission rate, there are still some issues that need to be addressed to help reduce readmission rates in heart failure patients, sepsis, pneumonia, other health conditions.

Sepsis and heart failure readmission rates are the two highest readmission rates at this facility. In the community, there are a total of two cardiologists, two interventional cardiologists, and one thoracic cardiovascular surgeon. Heart failure specialists are limited in this area which leads to delayed follow-up appointments and poor management of heart failure. Although many patients follow up with their primary care provider, this facility plays a vital role in helping manage patients with heart failure. I had the opportunity to talk with some heart failure patients

via telephone about the reason they had to return to the hospital within 30-days of being discharged from the hospital. The two main reasons were a lack of understanding of how to manage the condition and discharge medications that were not picked up from the pharmacy. Addressing the two main reasons that have been identified can potentially help lower the readmission rates from 3-5% with the ultimate goal of zero heart failure readmissions.

The Plan to Enhance the Future

In this DNP project, the plan was to implement a Patient Navigator Program that uses six evidence-based interventions to reduce heart failure readmissions and improve patient outcomes. The LACE (length of stay (L), acuity of admission (A), comorbidity (C), and ED visits in the previous 6 months (E) score was used to identify heart failure patients for readmission risk and to implement interventions. The LACE score can range from 0-to 19. A score of 0 – 4 is low, 5 – 9 is moderate, and a score of ≥ 10 is a high risk of readmission. The Patient Navigator Program targeted patients who have a score of ≥ 10. Interventions that were a part of the Patient Navigator Program include heart failure teach-back education (Appendix E), outpatient pharmacy prescription delivery to bedside, follow-up phone calls post-discharge with 24 hours and again at 30 days, discharge medication list education by the pharmacist, follow-up appointments made within 5 days of discharge, and home health referrals (Ingles, 2019). Many patients do not clearly understand heart failure, the prescribed medications, or the importance of following up with their health care provider which can increase the risk of readmission. Evidence has shown how a Patient Navigator Program has reduced readmissions and improved patient outcomes, and this is why it was utilized for implementation in this DNP project (Di Palo et al., 2017).

Problem Statement

Heart failure affects the lives of many patients throughout the United States. In 2014,

there were an estimated 1,068,412 emergency department visits, 978,135 hospitalizations, and 83,705 deaths due to patients with heart failure (Jackson et al., 2017). The financial penalty for hospitals for Medicare patients readmitted in 30 days for heart failure have hospitals trying to find out what to do about heart failure readmissions. Hospitals can now implement a Patient Navigator Program along with other evidence-based practices used to further reduce the readmission rates, enhance hospital performance, and improve patient outcomes. Some readmissions are unavoidable such as volume overload, IV diuresis, or an emergency surgical procedure. However, some circumstances can prevent readmission. Factors that are attributed to readmissions include shorter length of stay and multiple emergency department visits within 6 months of hospitalization (Di Palo et al., 2017). Implementing Patient Navigator Programs has shown a reduction in readmission rates. One study found <1.4% of hospitals reached a 20% reduction rate in 30-day readmissions (Di Palo et al., 2017). Identifying interventions that can reduce the heart failure readmission rate is essential for hospitals. In this DNP scholarly project, the DNP student implemented a Patient Navigator Program using six evidence-based practice interventions at an acute care facility in Mississippi to reduce the 30-day heart failure readmission rate and improve hospital performance.

Organizational "Gap" Analysis of Project Site

The acute care facility is located in a rural area that serves the residents of northeast Mississippi and west Alabama. The facility is the only acute care hospital in this county with several family practices and urgent care clinics. There are several healthcare specialties such as orthopedics, cardiology, urology, gastroenterology, nephrology, ENT, dermatology, general surgery, oncology, and other specialties. Currently, there is neither a heart failure clinic nor heart failure resources for the home setting in this area. In 2020, there were a total of 265 heart failure

cases at this facility with an average readmission rate of 19.25%. As of April 2021, there have been 132 heart failure cases with a 15.15% readmission rate compared to the national average at 22%. Heart failure is 2nd top ten primary diagnosis for Mississippi (Mississippi State Department of Health, 2016). The facility and the Patient Navigator Program utilize the American College of Cardiology (ACC) Foundation/American Heart Association (AHA) Guideline for the management of heart failure to educate patients on diet, exercise and medication, and follow-up care post-discharge. This facility follows many of the Agency for Healthcare Research and Quality (AHRQ) clinical practice guidelines, however, patient counseling and education along with exercise and rehabilitation needs improvement. Implementing the Patient Navigator Program helped the facility to identify high-risk heart failure patients, current practices, and implement interventions to reduce readmission rates (Di Palo et al., 2017).

Guidelines to follow in the Patient Navigator Program

The American College of Cardiology (ACC) Foundation/American Heart Association (AHA) Guideline follows evidence-based clinical practice guidelines to improve cardiovascular health. The evidence-based clinical practice guidelines provide recommendations to patients with or at risk of developing cardiovascular disease and are effective when followed by health care providers and patients. Implementing the Patient Navigator Program in this facility using the American College of Cardiology (ACC) Foundation/American Heart Association (AHA) Guideline reduces readmission rates and improves coordination of care between healthcare professionals and patients. The goal was to have an expected heart failure readmission rate of 18.85% for the fiscal year 2021, but the facility strives to have no heart failure readmissions. This DNP scholarly project was appropriate for the site to implement because the facility is below the national readmission average and could potentially benefit from the implementation of

the Patient Navigator Program to increase the quality of patient care and increase reimbursements.

Review of the Literature

The literature and search methods utilized were from PubMed, CINAHL, and OVID Medline. Using two MeSH terms navigator program and heart failure, 3595 articles were generated. The Boolean term was "and". The articles search were between 2016-2021 related to the navigator program and heart failure. All the articles found were exported to RefWorks. Most of the literature that was found was done in the United States, but some were from other countries. Keywords used were heart failure, readmission rate, navigator program, hospital. Five new articles were sent to the DNP student email account weekly on Sundays from the National Center for Biotechnology Information (NCBI) using the MeSH terms heart failure and hospital. There are many evidence-based practice interventions reviewed in the DNP student's research to reduce heart failure readmissions such as teach-back method with patient education, prescribing different heart failure medications, implementing transitional care programs, utilizing cardiac rehab, home health services, and many more.

Patient Navigator Program

The Patient Navigator Program was created in hospitals to decrease readmissions and improve patient outcomes. The LACE score was used to predict the risk of readmission within 30 days after hospital discharge. The LACE (length of stay (L), acuity of admission (A), comorbidity (C), and ED visits in the previous 6 months (E) score was used to identify heart failure patients for readmission risk and to implement interventions. The LACE score can range from 0-to 19. A score of 0 – 4 is low, 5 – 9 is moderate, and a score of ≥ 10 is a high risk of readmission. The Patient Navigator Program targeted patients who have a score of ≥ 10.

Identifying heart failure patients with high LACE scores upon admission help hospitals to meet the needs of the patients while in the hospital to ensure that patient is prepared to transition to their discharge disposition at the time of discharge. The Patient Navigator Program is an evidence-based practice intervention that is used to reduce heart failure readmission rates. The Patient Navigator Programs design and implement interventions that improve patient outcomes and decrease the patient's risk for readmission within 30-days. The principal investigator collaborates with the two nurse navigators and the pharmacist to design a quality improvement project implementing a checklist (Appendix C) with six evidence-based interventions for heart failure patients. These interventions included heart failure teach-back education (Appendix E), outpatient pharmacy prescription delivery to bedside, follow-up phone calls post-discharge with 24 hours and again at 30 days, discharge medication list education by the pharmacist, follow-up appointments made within 5 days of discharge, and home health referrals. Patients were followed from admission to discharge until all six interventions were completed. The Patient Navigator Program must be implemented in progressive care/step-down ICU with a high number of heart failure admissions. After identification and enrollment, the Patient Navigator Program team completes an intake assessment and clinical workup with interventions that started on admission and were completed by discharge. A study showed that a 30-day all-cause readmission rate was 17.6% for the Patient Navigator Program and 25.6% for a medical center and patients who received specific Patient Navigator Program interventions of education and follow-up the readmission rate was 10.3% and 6.1% (Di Palo et al., 2017). Hospitals implement the Patient Navigator Program into existing initiatives to further reduce the readmission rate. Hospitals across the United States use LACE scores to identify patients who are at risk for hospital readmissions within 30 days of discharge. Calculating the LACE score before the patient was

discharged allowed members of the health care team to identify patients at high risk for readmission. A Patient Navigator Program must have seven days of a week coverage in an institution to ensure the identification of services unique to each heart failure patient's complex needs (Di Palo et al., 2017). The Patient Navigator Program has already seen success with implementing best practices and care plans for heart failure patients.

Medication used to reduced heart failure readmissions

In conjunction with the Patient Navigator Program, a medication used to prevent a heart failure readmission is by prescribing Entresto. Entresto is a medication used to treat heart failure. The drug is a combination of Sacubitril/Valsartan. Although Enalapril is used for heart failure and other health conditions, heart failure hospital readmissions were reduced by 38% in patients who received Entresto instead of Enalapril for thirty days (Goldgrab et al., 2019). ACE inhibitors and ARBs have been the standard medications to treat heart failure for many years. Sacubitril/valsartan has a unique mechanism of action, in which synergistic effects of neprilysin inhibition with angiotensin receptor blockade improve efficacy and reduce heart failure readmissions (Sauer et al., 2019).

Home resources used to reduced heart failure readmissions

Home resources help reduce hospital readmissions. Ziaeian & Fonarow (2016) used a CardioMEMS device which is an implantable pulmonary artery sensor that can convey pulmonary artery pressure measurements. The CardioMEMS can indicate early heart failure worsening so that changes can be made to the patient’s treatment plan. The CardioMEMS was found to reduce heart failure hospitalizations by 37% in 15 months in patients who were previously hospitalized for heart failure and patients aged 65 years and older showed a 58% reduction in thirty-day readmissions with the CardioMEMS monitoring system (Ziaeian &

Fonarow (2016). The CardioMEMS is known to be effective and is now available for patients with heart failure. The CardioMEMS allows patients to transmit pulmonary artery pressure data from their homes to their health care providers, who then manage appropriate medication changes to reduce the likelihood of hospitalization (Ziaeian & Fonarow, 2016).

Telehealth is continuously growing throughout the United States health care system. An article that discussed a telehealth program for heart failure patients with home health that used a wireless tablet-based system that collected patients' vital signs that were preloaded with subjective questions related to heart failure symptoms and instructional videos to improve patient outcomes (O' Connor et al., 2016). The first year all-cause thirty-day heart failure hospital readmission rate was reduced to 19.3%. Telehealth follow-up can enhance patient care by efficiently identifying and treating patients most at-risk for readmission (O' Connor et al., 2016).

A study found by Bilchick et al (2019) developed a hospital-to-home intervention program for heart failure patients to follow up in a rapid clinic staffed by certified heart failure nurse practitioners to improve readmission cost and patient outcomes. Patients were scheduled within 1 week of their hospital discharge date and followed in the program for 30 days post-discharge. During this follow-up period, these patients had access to follow-up visits and clinical support. Follow-up visits focused on reviewing and assessing symptoms, vital signs, volume status, laboratory results, medication reconciliation, compliance with therapy, education, dietary and activity modifications, access to care, and home self-management strategies (Bilchick et al., 2019). There was a 24% reduction in readmission days within the first thirty days. The hospital-to-home intervention program is cost-effective, improves mortality rates, readmission rates, and readmission costs over 30 days.

Education

The last strategy was the teach-back heart failure education method. Nurses need new educational strategies to improve self-care behaviors and reduce readmissions in heart failure patients. This study aimed to determine the effect of the teach-back method on knowledge, performance, readmission, and quality of life in heart failure patients. A cardiac self-care questionnaire was used to assess the knowledge and practice of patients immediately after intervention and three months after patient discharge (Rahmani et al., 2020). Findings showed significant improvement in the patients' knowledge and performance immediately after teach-back education. Teach-back is an effective method to assess and teach self-care. However, effective teaching requires time for teaching. Teaching focused on when to report two- or three-pound weight gain in 24 hours and avoiding high salt foods (Rahmani et al., 2020).

As mentioned earlier, there are various ways to improve patient outcomes, improve hospital performance, and reduce the risks of hospital readmissions for heart failure patients in conjunction with the Patient Navigator Program. After the DNP scholarly project, the DNP student reviewed the current literature on how to reduce 30-day heart failure hospital readmissions. Currently, there was no new or the same literature that was found at the initial literature review.

Evidence-based Practice: Verification of Chosen Option

The primary aims of a Patient Navigator Program were to reduce 30-day heart failure readmissions to improve the transition of care by creating a comprehensive discharge plan, coordinating follow-up, and providing intensive disease and medication education along with the cost avoidance for preventable readmissions (Weeks et al., 2020). My PICOT question: Can the implementation of a patient navigator program reduce or prevent the 30-day all-cause heart failure readmission rate by 3-5% in six weeks?

Theoretical Framework or Evidence-based Practice Model

The Transitional Care Model (TCM) was designed to help improve outcomes and hospital readmissions. The Transitional Care Model (TCM) was developed by Mary Naylor (Appendix F). It focuses on comprehensive care starting at admission to discharge for heart failure patients who are at risk for health complications and readmissions. Also, TCM encourages continuity of care from the acute care setting to the community and home setting.

Key Components of the Transitional Care Model

Key components of this model include identification of patient goals, developing individualized care plans with the patient and interdisciplinary team, and providing continuity of care throughout settings (Maryniak, 2019). First, identification of patient's goals includes consulting with the patient about individual goals that they want to achieve and helping guide the patient to achieve their goal. Secondly, developing individualized care plans with the patient and health care team includes developing a care plan for the patient and the interdisciplinary team to find interventions that helped with completing their care plan before discharge. Lastly, providing continuity of care throughout settings includes ensuring that all disciplines that are involved are aware of what has been achieved and what needs to be addressed before the patient's discharge. TCM involves an interdisciplinary team to reduce hospital readmissions and provide communication among healthcare professionals. It emphasizes reducing the occurrences of readmissions and to improve patient outcomes.

Utilization of the Transitional Care Model

TCM has been used in studies such as discharge home visits and discharge follow-up calls which were successful in reducing re-hospitalization (Social Program That Work, 2021). I chose this model because it is led by nurses who are trained to care for patients with chronic

conditions and their focus is discharge planning. Using the TCM, the Patient Navigator Program identified patients who are at risk for hospital readmission by enrolling the patients in the Patient Navigator Program and implementing evidence-based practice interventions to reduce readmission rates and improve patient outcomes. The use of TCM helps improve outcomes and reduce readmissions which is the purpose of the Patient Navigator Program.

Goals, Objectives, and Expected Outcomes

Goals:

1. To reduce hospital all-cause heart failure readmission rates by 3-5% in 6 weeks.

Objectives:

• Implementation of the Patient Navigator Program by the facility within six weeks.

• The Patient Navigator Program addresses the facility and patient's discharge needs.

• The Patient Navigator Program will improve heart failure readmissions, enhance hospital performance, and improve patient outcomes.

•The Patient Navigator Program uses best practices to decrease 30-day heart failure readmission rates.

Expected Outcomes:

- The implementation of the Patient Navigator Program reduces 30- day all-cause heart failure readmission rate by 3-5% in 6 weeks.

Methods

This DNP scholarly project was to implement an evidence-based practice Patient Navigator Program in an acute care facility in Mississippi to reduce 30-day heart failure

readmission rates in six weeks.

Implementation of the Patient Navigator Program

The DNP student chose a progressive care unit at an acute care facility in Mississippi to conduct the Patient Navigator Program. Heart failure readmission rates were reviewed before the beginning of the Patient Navigator Program. The facility heart failure readmission rate was 17.45% at the start of the study. This facility was appropriate for conducting this project due to their increasing heart failure patient population. Next, the DNP student determined the cost of the Patient Navigator Program, found volunteers to participate in the Patient Navigator Program and assigned their roles, trained the nurse navigators and the pharmacist, and planned a start and end date to implement the Patient Navigator Program.

During the study, a total of fifty-five heart failure patients were admitted to the facility from October 15, 2021, to December 15, 2021, and a total of thirty patients who participated in the Patient Navigator Program. The LACE (length of stay (L), acuity of admission (A), comorbidity (C), and ED visits in the previous 6 months (E) score was used to identify heart failure patients for readmission risk and to implement interventions. The LACE score can range from 0-to 19. A score of 0 – 4 is low, 5 – 9 is moderate, and a score of ≥ 10 is a high risk of readmission.

The daily process of the Patient Navigator Program consisted of identifying patients with a LACE score greater than ten with a past medical history or new diagnoses of heart failure. After identification, the nurse navigator and pharmacist completed the enrollment by obtaining consent. Interventions included were heart failure teach-back education, outpatient pharmacy prescription delivery to bedside, follow-up phone calls post-discharge with 24 hours and again at 30 days, discharge medication list education by the pharmacist, follow-up appointments made

within 5 days of discharge, and home health referrals (Ingles, 2019). The patients were followed from admission to discharge until all six interventions were completed. All of the patients were tracked for 30 days after discharge to ensure that there were no readmissions.

Project Design

The DNP Project design was a Quality Improvement Project. Quantitative methods were used as a numerical analysis of data collected before and after the implementation of the Patient Navigator Program heart failure readmission rates along with the Patient Satisfaction Survey being observed. The data collection began by enrolling the patients in the Patient Navigator Program, tracking the patients for six weeks after discharge, monitoring for readmissions, and calculating the readmission rate from month to month. The survey consisted of five total questions. The survey served as a validation of nurse navigators and pharmacist-patient care performance and the effectiveness of the Patient Navigator Program.

Project Site and Population

The facility, located in Mississippi, has been caring for residents of Northeast Mississippi and West Alabama area for more than 45 years. There are more than 100 physicians and surgeons representing nearly every medical specialty. They strive to provide high-quality health care services and emphasize patient safety. The facility offers a full range of quality medical care services which include cancer care, cardiology, diagnostic, inpatient and outpatient psychiatric care, and women's services. The project was conducted on a progressive care unit. This unit provides care for patients with cardiovascular diseases and is also considered a step-down ICU unit.

The Patient Navigator Program included the principal investigator (DNP student), two nurse navigators, and one pharmacist. Recruitment of the nurse navigators and pharmacists was

done by asking for volunteers to participate in the program. The characteristics of the nurse navigators had to have leadership skills, caring, problem-solving skills, commitment to patient advocacy, experienced, willing to learn, patience, and critical thinking skills. All the nurse navigators had five years of experience in the progressive care unit and were experts in admitting and discharging heart failure patients' willingness to follow the guidelines of the Patient Navigator Program. The pharmacist was not required to have any experience to participate in the study. Patient enrollment into the Patient Navigator Program was based on specific criteria which included a LACE score greater than 10 with a past medical history of heart failure. The patient age range to participate in the study was 18-100. Pregnant women were not allowed to participate in the study.

The sample size included 30 participants. Five patients a week were enrolled in the program over six weeks. If the patient was discharged sooner than enrollment to the program, the principal investigator followed up with the patient outpatient. A total of fifty-five heart failure patients were admitted to the facility during that time, but a total of thirty patients consented to participate in the Patient Navigator Program.

The principal investigator interacted with the patients through face-to-face visits and telephone calls. Consultations with case managers and social workers for resources helped the heart failure patients such as home health referrals, charity assistance with medications, charity medical clinics, to meet the needs of the patient before discharge. The DNP student consulted with the Quality Improvement Department director and/or the administrative team to overcome barriers with my project such as revision of the project, changes in readmission rates, funding of the project, etc.

Measurement Instruments

To measure the outcomes of this project the following instruments were used: patient satisfaction survey, heart failure readmissions reports, heart failure admits and discharges reports, monthly readmission rate reports, and the Patient Navigator Program checklist.

Goal	Objectives	Measurement Tool	Outcomes
To reduce hospital all-cause heart failure readmission rates by 3-5% in 6 weeks.	• Implementation of the Patient Navigator Program by the facility in one year. • The Patient Navigator Program met the facility and patient's needs. • Results from the Patient Navigator Program (Appendix D) improved heart failure readmissions, enhanced hospital performance, and improved patient outcomes. •The Patient Navigator Program implemented best-practice interventions that decreased 30-day heart failure readmission rates.	•Patient Navigator Program checklist •Heart failure readmissions reports, heart failure admits and discharges reports and monthly readmission rate reports. •Patient satisfaction scores, heart failure readmissions reports, heart failure admits and discharges reports, and monthly readmission rate reports. •Patient Navigator Program checklist.	• The implementation of the Patient Navigator Program reduced the 30-day all-cause heart failure readmission rate by 4.77% in 6 weeks.

Data Collection Procedures

Data were collected by the principal investigator (DNP student) in Microsoft Excel. The data contained in the Microsoft Excel document included the patient's initials, gender, age, date of admission, enrollment date, interventions complete (yes/no), the date of discharge, and readmission in 30 days (yes/no). Also, the principal investigator collected the consent and Patient Satisfaction Survey that were stored in a locked cabinet in the quality improvement department.

A total of 30 patients participated in the Patient Navigator Program. The documents used to collect the data included the Patient Navigator Program checklist, heart failure readmissions reports, heart failure admits and discharges reports, and outcome measures which included the Patient Satisfaction Survey and the monthly readmission rate reports. The principal investigator used the Microsoft Excel document to record and track the data.

Data Analysis

For data analysis, the DNP student compared the readmission rates before the implementation of the Patient Navigator Program and the readmission rates six weeks after the implementation of the Patient Navigator Program. Readmission rates from month to month were analyzed to determine if the implementation of the Patient Navigator Program was reducing heart failure readmission rates by using a bar chart in a Microsoft Word document (Figure 1). Using the vertical bars on the bar chart, the readmission rates were illustrated. Also, the bar chart visually showed the highs and lows of the readmission rates over the last six months. Looking for the differences between the rates allowed the viewers to identify the pattern of the values easily. Because the bar chart has six different vertical bars, it helped to better visualize each readmission rate from month to month.

Cost-Benefit Analysis/Budget

The cost of the Patient Navigator Program was a total of $200.00. The supplies used were two cases of copy paper, folders, pens, pencils, paper clips, highlighters, and spiral notebooks. The principal investigator provided funding for the Patient Navigator Program. The facility currently is dealing with nurse shortage, increase in overtime payout, incentives for extra shifts, and physician recruitment due to the COVID-19 pandemic. The principal investigator did not want to cause another financial burden on the facility at the time of the implementation of the

Nurse Navigator Program. There was no overtime for the principal investigator, two nurse navigators, and the pharmacist. The two nurse navigators and the pharmacist participated in the program during their regular scheduled hours. The principal investigator, two nurse navigators, and the pharmacists provided patient care to heart failure patients, and being a part of this program helped enhance the care and improve patient outcomes. There is no cost to the patient or insurance company.

Timeline

After IRB approval, the DNP student began to train the two nurse navigators and the pharmacist regarding the Patient Navigator Program interventions. Data collection began October 15, 2021, through December 15, 2021(Appendix G). Each patient was tracked for 6 weeks after discharge.

Week 1: The DNP student trained the nurse navigators and the pharmacist.

Week 2: Started enrolling patients and implement in the Patient Navigator Program

Weeks 3-6: Continue to implement the Patient Navigator Program.

The data analysis, results, and dissemination of findings were completed by February 15, 2022.

Dissemination Plan

Dissemination of the QI project involved two presentations, one to the progressive care unit staff and a second one to the facility administrators which include the quality improvement director, chief executive officer, chief financial officer, chief nursing officer, and the chief of medical officer. A future presentation may be planned for the chief executive officer for the facility system. The purpose of the presentation was to compare the pre/post-implementation of the Patient Navigator Program, benefits outweigh the cost, easy to implement, recognize the need for change, cost-effectiveness, improves facility performance, and benefits the staff and patients.

The program must be promoted so that other health care facilities are aware of the benefits the program has to offer for heart failure patients and the facility. Finally, the manuscript will be submitted for publication in a peer-reviewed journal.

Ethical Considerations/Protection of Human Subjects

The University of Alabama (UA) Institutional Review Board (IRB) approval was obtained before initiating the project. All participants were protected by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) which, among other guarantees, protects the privacy of patients' health information (Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules, 2013). Additionally, the Standards of Care for practice in the admission agreement were carefully followed. All information collected as part of evaluating the impact of this project was aggregated data from the project participants and did not include any potential patient identifiers. The risk to patients participating in this project was no different from the risks of patients receiving standard care at this facility. Participant confidentiality was assured by coding the participants using unique identification letters. The list of participants and their identifying numbers were kept in locked filing cabinets in the Quality Improvement Director's office, only accessible to the principle investigator of the project. The evidence was destroyed at the end of the project.

Results

In this DNP project, the DNP student compared the heart failure readmission rates prior to the implementation of the Patient Navigator Program and the heart failure readmission rates six weeks after the implementation of the Patient Navigator Program (*Figure 1*). The Patient Navigator Program began on October 15, 2021, to December 15, 2021. A total of fifty-five heart failure patients were admitted to the facility during that period, but there was a total of thirty

patients (*Table 1*) that participated in the Patient Navigator Program. Three patients did not want to participate in the program because they were out-of-state residents. The facility's average heart failure readmission rate before the implementation of the Patient Navigator Program was twenty-five percent with the national heart failure readmission rate at twenty-three percent.

Over the six weeks, the heart failure rates for each month were October 12.44%, November 10.30%, and December 15.22% (*Table 2*) after the implementation of the Patient Navigator Program. Figure 1 shows the heart failure readmission rates three months before and after the implementation of the Patient Navigator Program. There was a 4.77% decrease (*Figure 2*) in the readmission rate of patients admitted with heart failure. There was an increase in the heart readmission rates during the month of December due to three patients that participated in the Patient Navigator Program being readmitted back to this facility but not related to heart failure. This facility follows an all-cause hospital readmission rates measure by the Centers for Medicare and Medicaid Services (CMS) guidelines for unplanned readmission for any cause to an acute care hospital within 30 days of discharge (Centers for Medicare and Medicaid Services, 2021). Even though the readmissions were not related to heart failure, the facility was still affected by the readmissions because it puts the facility at risk for not receiving reimbursement due to a readmission within 30 days of discharge and increases their readmission rates.

Interpretation/Discussion

It was determined that there was a 4.77% decrease in the readmission rate of patients admitted with heart failure. The patient's perception of the Patient Navigator Program played a vital role in making this project a success. There was a five-question Patient Satisfaction Survey was used to measure the performance of the program. All thirty patients that participated in the program completed a Patient Satisfaction Survey (*Figure* 3). When the patients were asked about

the professionalism of the program, two responses were satisfied but no other feedback was given to determine the reason for the response. When asked about the timing of the Patient Navigator Program, three of the patients felt as if the program was too time-consuming and needed shorter visit times. All thirty patients were very satisfied with the coordination of the Patient Navigator Program, the care by the health care professional, and the attentiveness towards concerns.

The administrators at this facility have not decided if the Patient Navigator Program will be implemented at this facility at this time. Currently, they are exploring other options such as the heart failure clinic that a new cardiologist to this area wants to explore. Developing the Patient Navigator Program helped reduce readmissions and improve patient outcomes for this facility to continue to strive to meet the needs of heart failure patients. As the DNP student who implemented the Patient Navigator Program, the goal was to help patients and families with the management of heart failure and reduce admissions to the hospital. Thirty-five hospitals have conducted the Patient Navigator Program across the country to avoid heart failure readmissions. Each facility used the evidenced-based interventions and hypothesized the approach to identify heart failure patients in the inpatient setting and reduce the 30-day all-cause readmission rates over seven months (Di Palo et al., 2017). The facility's heart failure readmission rate was 25% at the start of the study and by the end of the study, their heart failure readmission rate decreased down to 17.6%.

Conclusion

Heart failure continues to be one of the leading causes of hospital readmissions. Developing the Patient Navigator Program helped reduce readmissions and improve patient outcomes for this facility to continue to strive to meet the needs of heart failure patients. This

DNP project included comprehensive discharge planning, coordination, and education that is needed for heart failure patients at a low cost. The Patient Navigator Program was developed for patients and families with the management of this chronic illness and reduced admissions to the hospital. The implementation of this project helped heart failure patients to increase their quality of life and patient satisfaction.

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Tables

Table 1

Patient demographics (Study Participants Only)

Age (Years)	
Median (Min, Max)	63.5 (35, 88)
Sex	
Female	12
Male	18
Race	
African American	14
White	15
Other	1
Medical Coverage	
Insured	25
Uninsured	5

Table 2

Heart Failure Readmission Rates after the implementation of the Patient Navigator Program (Study Participants Only)

Heart Failure Readmission Rates by months	Readmission Rates %
October 2021	12.44%
November 2021	10.30%
December 2021	15.23%

- The mean average of heart failure readmission rate was 12.68%.

Figures

Figure 1

Comparison of before and after the implementation of the Patient Navigator Program

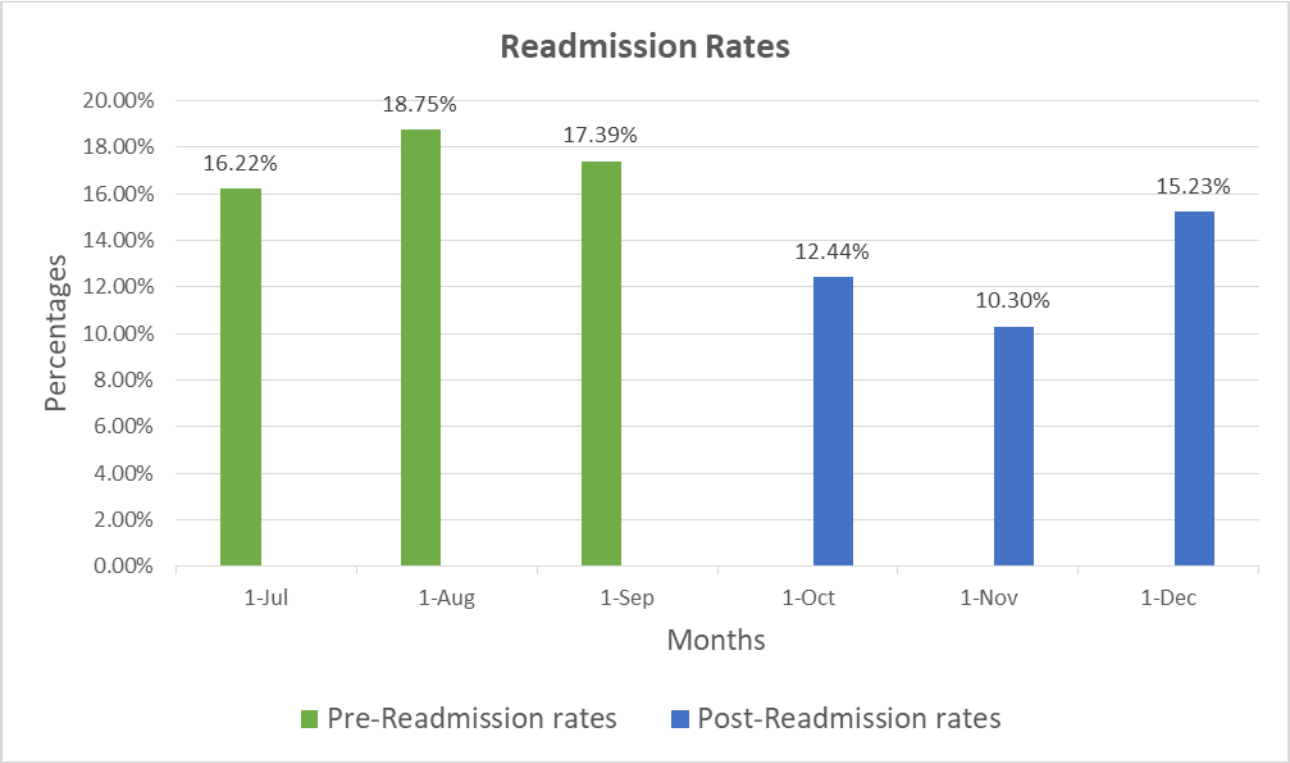


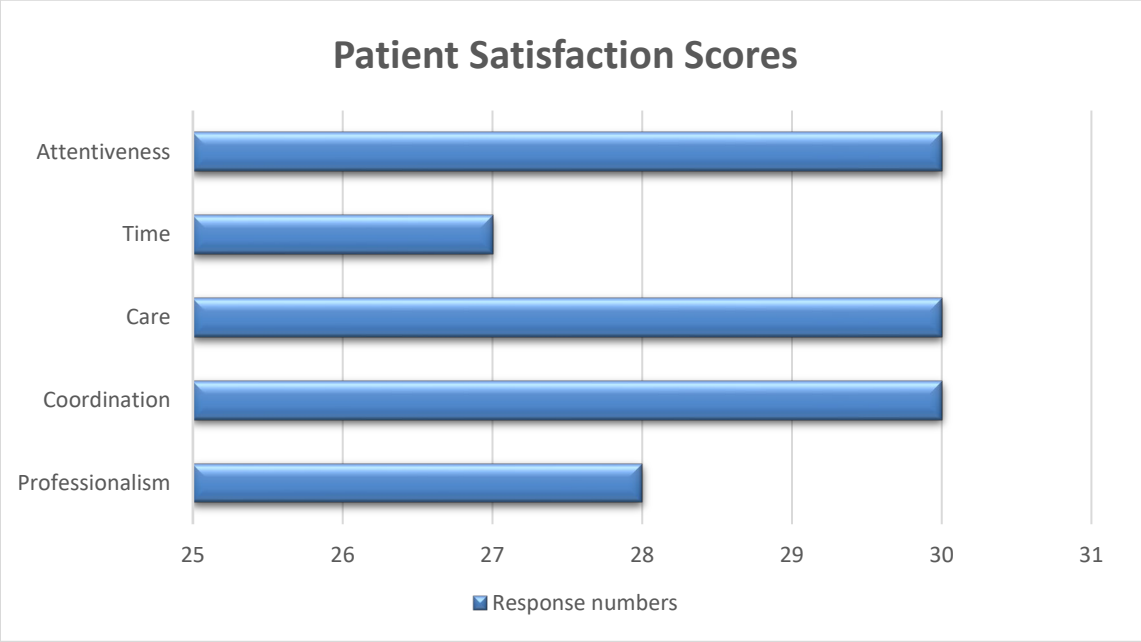
Figure 2

Reduction in Readmission Rates

Pre-Post=Sum	Pre-Readmission Rates: 17.45%	Post-Readmission Rates: 12.68%	4.77% decrease in the readmission rates.

Figure 3

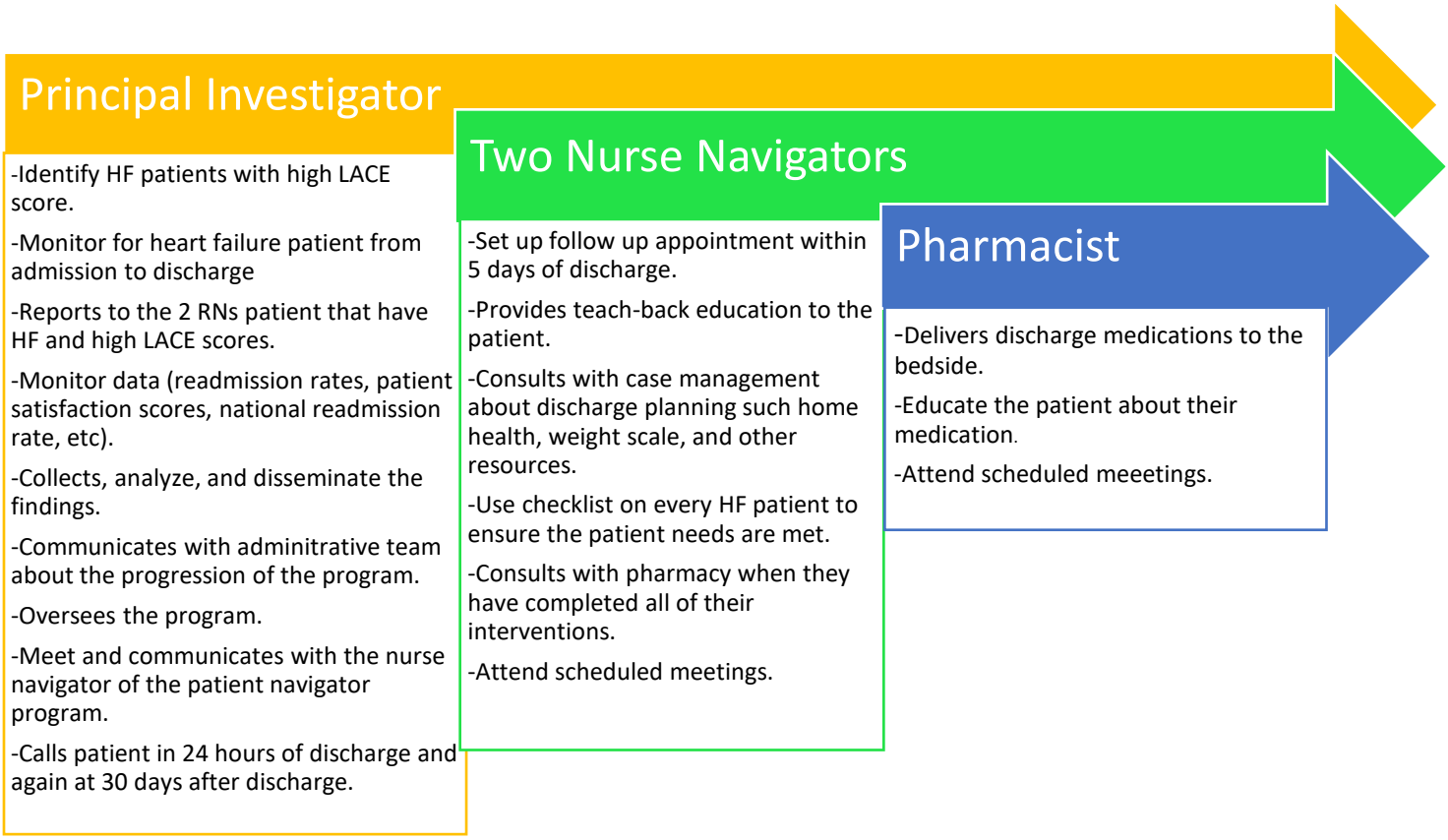
Patient Satisfaction Scores



Appendixes

Appendix A

Work Flow Chart



Appendix B

Patient Consent

INFORMED CONSENT FOR PARTICIPATION IN A RESEARCH STUDY

Title of Study: Implementation of a Patient Navigator Program to reduce 30-dayHeart Failure Readmission Rate

Protocol No.:

Sponsor:

Investigator: Jalenza McGee, MSN, APRN, FNP-C

Participating Investigators: Mary Ables, Ph.D., Shannon Roberts, RN, and Hayden Hudspeth, RN

Telephone: 662-435-3755

Key Information

You are being asked to volunteer for research.

Below is some key information to keep in mind when thinking about why youmay or may not want to be in the research. Additional information and detail will follow later in this document where indicated.

If you agree to be in this study, the researchers will tell you about any important new information that is learned during this study, which might affect your condition or your willingness to continue participation in this study.

Introduction	The purpose of this form is to provide you with information that may affect your decision as to whether or not to participate in this research study. The person performing the research will answer any of your questions. Read the information below and ask any questions you might have before deciding whether or not to take part. If you decide to be involved in thisstudy, this form will be used to record your consent.

Voluntary Participation	You do not have to be in this research. It is your choice to decide whether or not you want to take part. If you choose not to take part or choose to stop taking part at any time, there will be no penalty to you or loss of benefits to which you are otherwise entitled.

Purpose	The purpose of this research is to implement a patient navigator program composed of one patient navigator, two registered nurses, and one pharmacist that provide six evidence-based practice interventions (heart failure teach-back education, outpatient pharmacy prescription delivery to bedside, follow-up phone calls post-discharge with 24 hours and again at 30 days, discharge medication list education by the pharmacist, follow-up appointments made within 5 days of discharge, and home health referrals) to reduce the 30-day all-cause readmission rate for heart failure patients with high L-Length of Stay, A-Acuity of Admission, C-Comorbidities, E-Emergency Department visit scores. The LACE score (L-Length of Stay, A-Acuity of Admission, C-Comorbidities, E-Emergency Department visit) can range from 0-19. A score of 0 – 4 = Low; 5 – 9 = Moderate; and a score of ≥ 10 = High risk of readmission. Patients with high LACE scores (L-Lengthof Stay, A-Acuity of Admission, C-Comorbidities, E-Emergency Department visit) 10 or greater were followed from admission to discharge and six interventions were completed to prevent 30-day hospital readmission.
Why you are being asked to participate	You are being asked to take part in this study because you have a history or have been newly diagnosed with heart failure.
Number of Participants	About 25 people will take part in this research at Baptist Memorial Hospital Golden Triangle.
How long you will be in the study	You will be in this research study for about six weeks.
What you will be asked to do	While you are in the study you will be involved in different interventions and complete a patient satisfaction survey at the end of the study with no risks. The interventions include • Heart failure education. • Outpatient pharmacy prescription delivery to bedside. • Follow-up phone calls post-discharge with 24 hours and again at 30 days. • Discharge medication list education by the pharmacist. • Follow-up appointments made within 5 days of discharge. • Home health referral (if needed).
Possible Risks	Risk of loss of confidentiality.
Possible Benefits	You will receive no direct benefit from participating in this study; however. The study may help reduce 30-day heart failure readmission.

Costs	There is no cost for participating in this study.
Payment	You will not receive payment for taking part in this study.

Alternatives to participation	Your alternative to being in this study is to simply not participate.
Ending Study Early	There are some reasons you may withdraw, or be removed early from this study, for example, due to medicalissues.
Protection of your information	We will make every effort to protect the confidentiality of study records that identify you, but we cannot guarantee total confidentiality. They may be viewed by the research team and other people within Baptist who help oversee research. If information from this study is published or presented at scientific meetings, your name and other identifiable information will not be used.
Contacts	**If you are having a medical emergency, call 911 or go to an emergency room right away. You should let emergency personnel or providers know that you are taking part in this study.** **For questions about the study or research related medical issues:** • Main Investigator- Jalenza McGee at 662-435-3755 or (jalenza.mcgee@bmhcc.org • Sub-Investigator- Dyshone Robbins at 662-244-2985 or (dyshone.robbins@bmhcc.org) • Research Coordinator-Mary Ables (mary.ables@bmhcc.org), Shannon Roberts (shannon.roberts@bmhcc.org), and Hayden Hudspeth (hayden.hudspeth@bmhcc.org). **If you need to contact someone other than the study personnel about a concern or your rights as a research subject:** • Baptist Institutional Review Board at 901-226-1677 or 901-226-1678 **If you would like to speak to a person who is not affiliated with this research study to discuss problems, concerns, or questions, or to obtain information or offer input:** Rev. Anthony Burdick, Director of Pastoral Care, Baptist Memorial Health Care Corporation at 901-226-5025

Again, remember that your participation in this research is voluntary. Refusing to participate, or stopping your participation, will not result in any penalty or loss of benefits to which you would otherwise entitle.

Additional Details: What will you be asked to do?

In addition to the study events described above, we want you to know the following:

Time required: The study will require about 2 hours to six weeks of your time.

Could your information be used for future research without asking for your permission?

No. The information collected as part of the research, even if identifiers are removed, willnot be used or distributed for future research studies.

COSTS FOR PARTICIPATION
The study will be provided to you free of charge.

Additional Detail: In case of Injury

If you think you have been hurt by taking part in this study, tell the study investigator assoon as you can by calling *Jalenza McGee* at *662-435-3755*

Baptist Memorial Hospital Golden Triangle will be open to you for treatment and/or hospitalization. Baptist Memorial Hospital Golden Triangle has funds for patient compensation of any kind. Therefore, they cannot provide payment for study injuries.

You and/or your insurance company will be responsible for the cost of your hospitalization.

Additional Information: PROTECTION OF YOUR INFORMATION (CONFIDENTIALITY):

General:

Your paper research records will be stored in locked file cabinets and will be accessible only to research personnel and the specified entities listed in this section, except as required by law (such as reports of child abuse, plans to commitsuicide, etc.).

Your electronic research records will be computer password protected and accessible only to research personnel and the specified entities listed in this document, except as required by law (such as reports of child abuse, plans tocommit suicide, etc.).

Protection of Protected Health Information (PHI) under HIPAA)

What is the HIPAA Privacy Rule?
The "Privacy Rule" is a Federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that protects certain health information. It was issued by the government to make sure that your medical and health information is protected

and not shared with others without your permission. Participants in research studies may be protected by this regulation. Most participants in research studies will need to sign an informed consent form which includes an Authorization for the use and release of certain health information.

What is "Protected Health Information" (PHI)?

Protected health information (PHI) is information about you and your health. Examples of protected health information (that may be collected and used in thisstudy) are:

- Personal information such as your name, initials, social security number,date of birth, age, address, race, and sex
- Information that describes your disease and/or condition
- History and treatment of your disease and/or condition
- Past and current medical history
- Other medical conditions that may affect your treatment
- Medications that you may be taking or have taken in the past
- Medical data like laboratory test results, tumor measurements, CT scans, MRIs, X-rays, EKGs, and pathology results
- Information about side effects you may have and how they were treated
- Follow-up information about your general health and disease after your treatment.

Why this information is being used and/or given to others?

Information is collected for this study:

- To do the research
- To study the results of the research, and
- To see if the research was done right.

HIPAA Authorization

To take part in this study, we need to obtain your health informationfrom your medical providers. Your signature on this form which includes this HIPAA Authorization will allow us to get access to that information. We are committed to respecting your privacy and to keeping your personal and health information confidential. When choosing to take part in this study, you are permitting us to use your personal information that includes health information in your health care records and information thatcan identify you. For example, personal information may include your name, address, phone number, medical diagnosis, or social security number.Your health information and personal information we may collect and use for this study include:

All information being collected for this study: demographics including raceand age, medical history, admission history, medications, and survey.

This also includes any information collected about a medical issue caused by a study activity.

Cancellation of Authorization

Your authorization for the use and/or disclosure of your health informationwill end on December 31, 2021, or when the research project ends, whichever is earlier. List a specific date on which the authorization will expire on December 31, 2021. If you are uncertain, choose a date that provides plenty of time for your work to be completed.

If you terminate this authorization, continued use of your PHI already obtained before the termination is permitted and its use is necessary for completing the research. However, PHI collected after your termination ofthis authorization may not be used in this study. If you refuse to sign this authorization, you will not be able to participate in this research study. If you terminate this authorization, then you will be withdrawn from the study.You may terminate this authorization in writing at any time by contacting the investigator Jalenza McGee by sending a letter to this address:

- Implementation of a Patient Navigator Program to reduce Heart Failure Readmission Rate
- 2520 5th Street North Street
- Columbus, Mississippi 39705

I understand that the medical provider may not make my treatment conditional on whether or not I sign the authorization.

I understand that this authorization is voluntary and that I may refuse to signthis authorization. I understand that my refusal to sign this authorization does not affect payment for services, my ability to obtain treatment, or my eligibility for benefits or enrollment.

For this study, certain people will need access to your personal information.All the people who will need access to your personal information may not be required by law to protect it. However, they will all protect it to the bestof their ability. Therefore, there is the potential risk of loss of confidentiality.Every effort will be made to keep your information confidential, however, this cannot be guaranteed.

The following people may have access to your personal information:

- Research personnel employed at Baptist Memorial Health Care Corporation or any of its affiliates include Jalenza McGee, Dyshone Robbins, Mary Ables, Shannon Roberts, and Hayden Hudspeth.
- Institutional Review Boards (ethics committees that review research)

To the extent allowed by law, we limit the viewing of your personalinformation to people who have to review it. We cannot promise complete secrecy.

Additional Information:

LEAVING THE STUDY EARLY

If you withdraw or are removed from the study, no new data will be added to the database once you withdraw.

CONSENT SIGNATURES TO FOLLOW ON NEXT PAGE

CONSENT TO PARTICIPATE

The research study, procedures, risks, and benefits have been explained to me. I have readall of the above, been allowed to ask questions, and my questions have been answered to my satisfaction. I voluntarily agree to participate in this research study. I willbe given a copy of this signed and dated consent form for my records. I do not give up any of my legal rights by signing this consent form.

_____
Name of Adult Participant (printed)

_____ _____
Signature of Adult Participant Date/TimeOr

_____
*Legally Authorized Representative (printed)

_____ _____
Signature of the Legally Authorized Representative Date/Time

_____
Relationship to patient

_____
Name of Person Obtaining Consent (printed)

_____ _____
Signature of Person Obtaining Consent Date/Time

*If authorization is to be obtained from a legally authorized representative (e.g., parent(s),legal guardian, or conservator) a description of his/her authority to act for the participant isalso required.

Appendix C

Checklist

- Consent to participate in the patient navigator program.
- Enrollment is complete in the patient navigator program.
- Heart failure teach-back education.
- Outpatient pharmacy prescription delivery to bedside.
- Follow-up phone calls post-discharge with 24 hours and again at 30 days.
- Discharge medication list complete and medication education by the pharmacist.
- Follow-up appointments made within 5 days of discharge.
- Home health referrals.
- Patient survey satisfaction complete before discharge.

Appendix D

Patient Satisfaction Survey

How satisfied were you with the following during your treatment at our medical facility?

	Very Satisfied	Satisfied	Neutral	Unsatisfied	Very Unsatisfied
The professionalism of our staff	○	○	○	○	○
Coordination of the patient navigator program	○	○	○	○	○
Care provided by healthcare professional	○	○	○	○	○
The time that a healthcare professional spent with you	○	○	○	○	○
Attentiveness towards concerns	○	○	○	○	○

Appendix E

Teach-back Education Method

Weight Management
- Weigh yourself every morning (before eating and after going to the bathroom) and bring a list of your weights to your appointments.
- If your weight goes up 2 pounds in one day or 5 pounds in one week, you should call your health care provider.

Low Sodium Diet
- Limit their salt to 2500-3000 mg per day.
- Avoid salt substitutes, canned or processed foods, and salted snacks.
- Consider buying or checking out a cookbook from the library such as American Heart Association Low Salt Cookbook.

Medication Management
- Take your medications as prescribed and refill your prescriptions on time.
- Let your health care provider know if you are not able to get or take your medications.
- Bring all medications, including those you buy "over-the-counter" to your appointments to review with your health care provider.

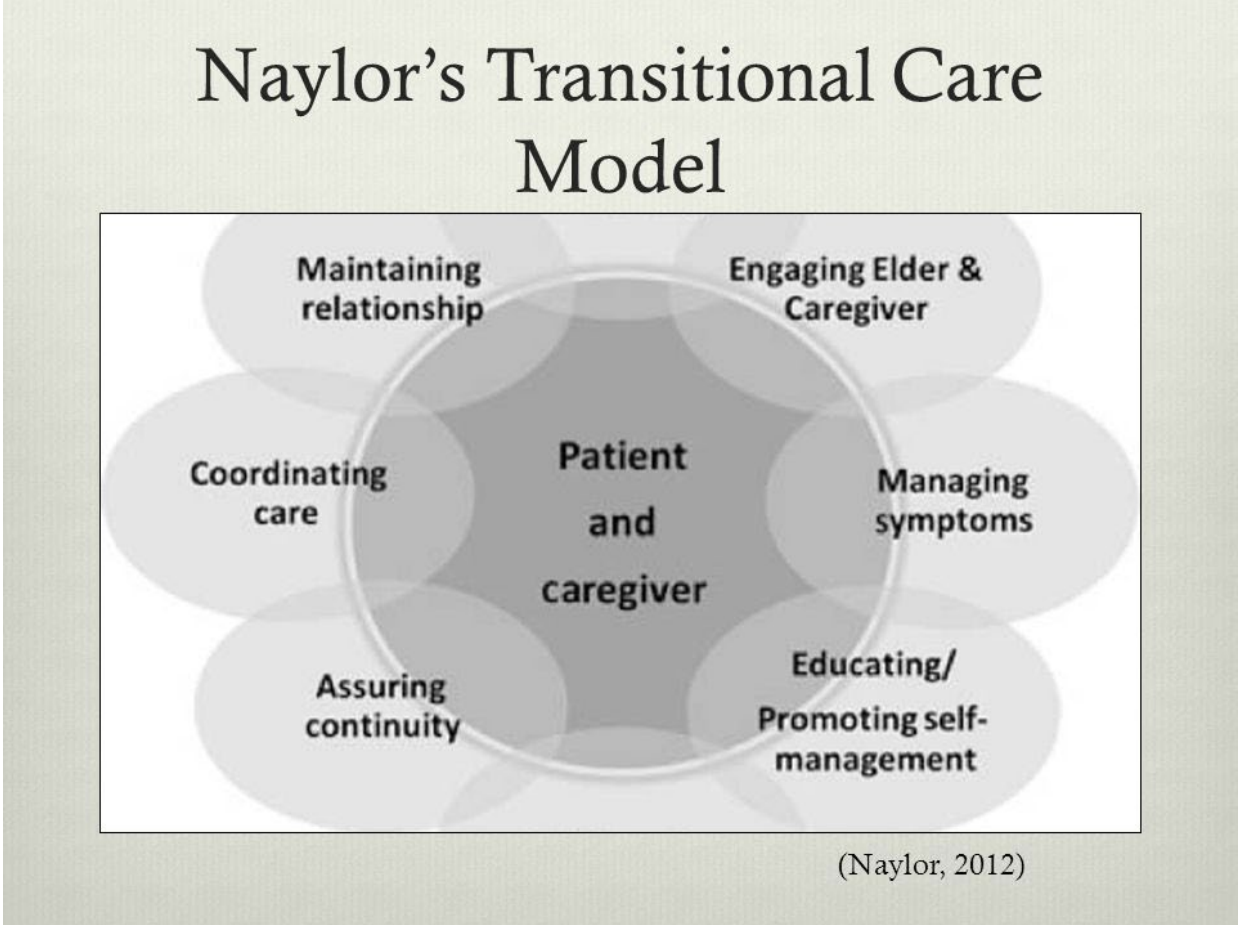
Exercise & Activity
- Start slow and easy. For example, 5 – 10 minutes a day and increase gradually. If you cannot exercise every day, then try at least 3 days a week. You do not need to exercise all at one time.
- Examples of exercises: walking, swimming, dancing, or yoga.

Symptom Recognition
- Notify the doctor if you are experiencing shortness of breath with activity or when lying down, fatigue and weakness, swelling in the legs, ankles, and feet, rapid or irregular heartbeat, reduced ability to exercise, persistent cough or wheezing with white or pink blood-tinged mucus, rapid weight gain from fluid buildup, and chest pain.

Discharge & Follow-Up Management
- Keep all appointments with your health care providers. Write down any questions you have and bring them to your appointments

Appendix F

Mary Naylor's Transitional Care Model



Appendix G

Timeline

Weeks	Tasks
Week 1	• Train the navigators and the pharmacist.
Weeks 2-6	• Implement the Patient Navigator Program. • Started enrolling the patients in the Patient Navigator Program. • Collect data
Week 6	• End the Patient Navigator Program. • Follow each patient for 6 weeks post-discharge and track readmission rates and analyzed the results. • Start analyzing and Disseminating the findings.

Appendix H

Date of Correspondence: October 06, 2021
Principal Investigator: Jalenza McGee

IRB Number: 21-041
Submission Type: Initial
Study Title: Implementation of a Patient Navigator Program to reduce 30-day Heart Failure Readmission Rate

Determination Date: October 06, 2021

Progress Report Due Date: October 05, 2022
Level of Review: Exempt
Exempt Review Categor(ies): 3(i)(A)

Regulatory Oversight: 2018 Common Rule

IRB Determination: **EXEMPTION GRANTED | PROGRESS REPORT REQUIRED**

The Baptist IRB reviewed the materials listed below in reference to IRB submission number 21-041 and determined the submission qualifies for exemption from federal regulations.

Documents Reviewed:

- Baptist ICF.docx (Informed Consent Document)
- citiCompletionReport10283867 (1).pdf (Human Subject Protection Training (CITI))
- citiCompletionReport10523598-Shannon Roberts.pdf (Human Subject Protection Training(CITI))
- citiCompletionReport8649801-Hayden Hudspeth.pdf (Human Subject Protection Training (CITI))
- citiCompletionReport9238364-Mary Ables.pdf (Human Subject Protection Training (CITI))
- DNP proposal (Other)
- DNPProject-Jalenza McGee NUR 703.docx (Supporting Documentation)
- IMG_2178 (1).jpg (NIH Financial Conflict of Interest (FCOI) Cert)
- IMG_2180.jpg (Professional License)

6027 Walnut Grove Road, Suite 305 Memphis, Tennessee 38120
Phone: (901) 226-1677 or (901) 226-1678 | Fax: (901) 226-1680
Baptist Memorial Health Care Corporation
has an approved Federalwide Assurance with theDepartment of Health and Human Services: FWA00004299.

HRPP 902 Exempt Initial Progress Report Required

- JalenzaMcGee_citiCompletionReport.pdf (Human Subject Protection Training (CITI))
- NUR 795_796_797 DNP Clinical Packet_2.23.2021.pdf (Protocol)
- Patient Satisfaction Survey_IRB.docx (Survey Instrument)
- Revised ICF - highlighted.docx (Informed Consent Document)
- Revised ICF.docx (Informed Consent Document)

Any Applicable Subpart or Special Determinations:

- Not Applicable

For Category(ies) 2(iii) or 3(i)(C) Only:
If the Exempt Review Category(ies) above is/are 2(iii) or 3(i)(C), the IRB conducted the required limitedIRB review.

For All Category(ies):
All research activities must be conducted in accordance with the documents above. Any changes to the research must be reviewed and approved by the Baptist IRB Office **before** implementation, except whennecessary to eliminate an apparent immediate hazard to the participant(s). In which case, the changes must be reported immediately.

If the study is not ***complete*** before October 05, 2022, you must submit a **Progress Report** to the IRB 30days before October 05, 2022 to satisfy Baptist institutional requirements and prevent your study frombeing interrupted.

If you do not receive IRB acknowledgment before October 05, 2022, you must stop all research activitiesassociated with this study unless the Board determines that continuing certain activities is in the best interest of participants.

In studies where obtaining informed consent/permission/assent is required, be sure to continue to monitor the participant's willingness to be in the study throughout their duration of participation. Onlyuse the current, IRB-approved stamped documents for the consent process. All consent documents in this study must be obtained and retained as outlined in Baptist HRPP Policies and Procedures.

Unanticipated problems must be reported to the IRB following Baptist HRPP Policies and Procedures.

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Any complaints or issues of non-compliance must be reported immediately to the IRB. Refer to the Baptist HRPP Policies and Procedures for additional information on interim reporting responsibilities.

If this research is covered by a Certificate of Confidentiality (CoC), you are responsible for compliancewith COC requirements.

Based on the submission, this research is subject to the policies and procedures of Baptist Memorial Health Care Corporation (BMHCC), each of the entities in which it is the sole corporate member, and applicable State laws. As the Principal Investigator, you are responsible for ensuring compliance with allapplicable regulations and requirements.

Reminder:

All contracts, agreements, and data security assessments need to be completed *before* the start of anyresearch activity.

If you have any questions or comments about this correspondence, feel free to contact the IRB Office at Baptist.IRB@bmhcc.org.