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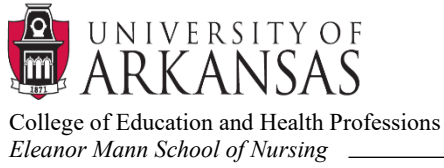
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**Effectiveness of a Frailty Assessment Index to Predict Early Readmission Rates in Frail  
and Older Adult Renal Transplant Patients**

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## Abstract

**Background:** Renal transplantation is a complex intervention integrating both medical and surgical modalities, and is considered the treatment of choice for many individuals with end-stage renal disease. The complicated care of patients undergoing renal transplantation puts them at risk for adverse outcomes including infection, allograft loss, and a greater risk for some types of cancer. Evaluating patients to ensure they have the ability and support to cope with the stress of surgery and recovery, is an important part of determining the most appropriate candidates to receive the limited supply of organs available. Frailty has increasingly been identified as a predictor of poor surgical outcomes, mortality, and hospital readmissions. A review of literature was conducted to analyze the impact of frailty on renal transplantation outcomes, as well as the usefulness of the 5-Item Modified Frailty Index to predict 30-day readmission rates among renal transplant recipients.

**Purpose:** The project purpose was to evaluate the effectiveness of the 5-Item Modified Frailty Index (mFI-5) to predict 30-day re-admission rates among renal transplant recipients and was accomplished through a retrospective chart review performed at an inpatient hospital transplant institute in Shelby County, Tennessee, and included 194 electronic medical records related to patients who had undergone renal transplantation between December 2020 and December 2021.

**Results:** Data from this retrospective review revealed individuals scoring two or greater on the mFI-5 screening tool, had a significantly higher readmission rate (51.4%) compared to the readmission rate (27.2%) for individuals scoring less than two.

**Conclusion:** The results of this project indicate that mFI-5 does have utility in the evaluation of frailty in renal transplantation patients and warrants further study to determine its full application and value.

*Keywords:* frailty, renal transplantation, complications, early readmission

## **Effectiveness of a Frailty Assessment Index to Predict Early Readmission Rates in Frail and Older Adult Renal Transplant Patients**

The purpose of this DNP quality improvement project was to identify risk factors contributing to post-transplant early readmissions in the frail adult renal transplant population, using a frailty assessment tool, in order to determine opportunity for proactive interventions aimed at improving outcomes. It has been noted that across the world, life expectancy is increasing and frailty is progressively being recognized as a significant public health concern (Adia et al., 2020).

Frailty has been defined as a syndrome characterized by diminished strength, endurance, and reduced physiologic function, increasing an individual's vulnerability for developing increased dependency, as well as increased risk of mortality, when confronted with a stressor (Harhay et al., 2020). A primary goal of this project was to contribute to the development of a deeper understanding of how frailty impacts outcomes in the adult kidney transplant patient, specifically early readmission, in order to address gaps in care. Research has shown that frail individuals are almost half as likely to be listed for kidney transplantation compared with non-frail individuals, independent of age and other demographic factors, and frailty is also associated with a lower rate of transplant (Haugen et al., 2019). This group of patients is vulnerable not only from the standpoint of listing, and approval for transplant, but are also at greater risk for poor outcomes post-transplant. Frailty has been identified as a distinct syndrome manifesting itself in decreased physiologic reserves and decreased resistance to stressors, resulting in lower referrals for transplant, higher rate of waitlist mortality, and poorer outcomes post-transplant (Haugen et al., 2016). The 5-Factor Modified Frailty was evaluated to determine its predictive value in identifying characteristics unique to the frail adult population which may contribute to poor renal

transplant outcomes. In analyzing the relevance of this tool to reflect frailty, a plan can be established to promote effective team discussion and decision-making, improve opportunities for individuals in this population to qualify for transplant, and enhance more favorable outcomes post-transplant. By validating the 5-Factor Modified Frailty Index to be an effective predictor of postoperative complications in the older adult population it can be established as credible for future use to study frailty and for clinical assessment and decision-making (Subramaniam et al., 2020).

## **Background and Significance**

### ***Renal Transplantation in the United States***

In spite of the continuing lack of available organs for transplant in relation to candidates in need, Organ Procurement and Transplant Network (OPTN) Scientific Registry of Transplant Recipients (SRTR) data from February 2021 noted that the number of kidney transplantations reported in the United States has increased each year since 2015 and reached its highest number to date at 24,273 in 2019 (Hart et al., 2021). As of July 2021, 24,893 renal transplantations had been performed in the United States, yet 90,228 individuals remain on the kidney transplant waitlist (Hart et al., 2021). With so many people in need of organ transplantation, it is critically important that patients receiving a renal transplant achieve the maximum benefit from their organ. It is estimated that frailty is present in up to 35% of patients with end stage renal disease, and up to 20% of kidney transplant recipients are frail, increasing their risk for poor outcomes post renal transplant (Haugen et al., 2019). As many of these individuals will be referred for renal transplant, identifying ways to evaluate the unique characteristics related to frailty, and addressing the associated distinct needs should be a priority to better support successful transplantation and recovery.

### ***Pre-Transplant Referral of Frail and Older Adults***

A systematic review of literature identified gaps in care related to identifying and addressing disparities in the renal transplant referral system for frail and older adult with end stage kidney disease. Despite the fact that elderly patients make up half of the incident dialysis patients in the United States, and individuals greater than 65 years of age represent the fastest growing group on the kidney transplant waitlist, the trend shows that the percentage of elderly patients wait-listed or transplanted within the first year of dialysis is 9.9%, which is lower compared with the overall rate of 15.8% and much lower than their younger counterparts (Singh et al., 2016). It was also determined that despite the benefits of kidney transplant, less than 30% of prevalent dialysis patients are wait-listed for transplant, and age is one of the three most common factors regarded by nephrologists as relevant in not referring patients for kidney transplant evaluation (Bartolomeo et al., 2019). There is a clear need that exists for more studies in this population to enhance care through improving the pretransplant evaluation process to provide opportunities to optimize patients for transplant, provide more data to guide management of immunosuppression, and individualize post-transplant care (Singh et al., 2016).

### ***Renal Transplantation in the Frail and Older Adult***

While there is no universally accepted definition for frailty, it has been described as a complex age-associated syndrome resulting from a decrease in multiple physiological systems which leads to an impaired ability to effectively respond to stressor events (Adja et al., 2020). Additionally, research has shown that frailty is a state of vulnerability and is one of the most important risk factors for detrimental health outcomes including mortality among older adults (Palliyaguru et al., 2019). Frailty is associated with falls, hospitalizations, poor cognitive function, poorer health-related quality of life, and higher rate of mortality (Haugan et al.,

2019). For the frail and older adult individual with chronic or end stage renal disease, kidney transplantation is a treatment option beneficial in promoting a healthier and longer life. The physiologic impairment associated with the pathology of frailty contributes to poor quality of life and higher risk for complications for these individuals in the pre-transplant and post-transplant periods. Research has shown that frailty at the time of kidney transplant evaluation is associated with a 2.8-fold higher risk of fair or poor health-related quality of life and a 2.9-fold increased risk of declining health-related quality of life while waiting for transplantation, as well as, a 2.2-fold greater odd of wait-list mortality (Kobashigawa et al., 2019). In order to actively respond to the unique needs of this population, it is important to discover effective ways to identify patients with characteristics contributing to frailty to alleviate the complications that may potentially be experienced post-transplant. Hospital readmissions within 30 and 90 days post-renal transplant result in clinical and financial burdens for kidney transplant recipients and the healthcare system at large (Famure et al., 2021). In the post-transplant period, research shows that frail kidney transplant recipients are at 2.1-fold increased risk of delirium following kidney transplantation, a 1.6-fold higher risk of longer length of stay, a 1.9-fold higher risk of delayed graft function, a 1.6-fold higher risk of early hospital readmission, a 1.3-fold higher risk of immunosuppression intolerance, and a 2.2-fold higher risk of mortality (Kobashigawa et al., 2019). Developing effective pathways to better understand and treat frailty can promote opportunities for better outcomes and resource utilization.

### ***Assessing Frailty in the Older Adult***

While kidney transplantation may provide life-saving benefits, it is important to note that frailty is a predictor of adverse outcomes in individuals undergoing kidney transplantation



(Chu et al., 2019). In a multi-center prospective, longitudinal study of 2,086 kidney transplant candidates, Fernandez and colleagues noted that 51% of the cohort had a high burden of comorbidity, more common among frail and intermediately frail kidney transplant candidates, and suggest that measuring both frailty and comorbidity are important for improved risk prediction (2019). Identifying potential reversible components contributing to frailty associated with organ failure could allow for education of transplant candidates and referring providers, identify opportunities for intervention, optimize timing for transplantation and improve outcomes (Kobashigawa et al., 2019). In addition to improving outcomes for this population, there is also a need to discover more effective ways to prepare and support these individuals for the challenges and responsibilities they will encounter related to self-care in both the acute immediate post-transplant hospitalization and early home recovery period and in long-term maintenance. Currently, advanced age alone is not a contraindication to receiving a renal transplant; however, older kidney transplant recipients are at greater risk of cognitive impairment, frailty, comorbidities, immunosuppression related problems, and chronic allograft failure (Pinter et al., 2017). More specific investigative methods of evaluation and subsequent care that focus on the unique set of problems in this population including frailty, cognitive impairment, and comorbidities will help to advance renal transplant as an important treatment option and improve outcomes in this group of patients. A clear need exists for more studies in this population to improve the pre-transplant evaluation process to provide opportunities to optimize patients for transplant, provide more data to guide management of immunosuppression, and individualize post-transplant care (Singh et al., 2016). Though frailty has been understood clinically as a state of increased vulnerability to stressors characterized by slower or incomplete recovery from infection, injury, surgery, or psychosocial distress, there is

no consensus on an operational definition (Martin et al., 2020). Implementation of an effective evaluation tool to simply and effectively assess this population of patients during the immediate pre-transplant and immediate post-transplant timeframes can lead to improved evidence-based practice. Risk stratification, using a criteria-based frailty assessment, can increase the opportunity for improving patients' physiology prior to surgery through pre-habilitation, such as nutrition, and exercise regimes, as well as through planning for effective rehabilitation after surgery (Panayi et al., 2019).

### **Problem Statement**

The problem statement for this DNP quality improvement project is that frail and older adult renal transplant patients experience complications post-transplantation, resulting in early hospital readmission and increased morbidity, which can be prevented through early risk identification and proactive interventions. Research shows that the best strategy for successful renal transplantation in frail and older adult patients is to individualize their care (Singh et al., 2016). Though the pre-transplant evaluation and listing process is extensive, little focus has been placed on specifically identifying characteristics unique to the frail and older adult population for risk stratification and proactive interventions.

### **Purpose Statement**

The purpose statement for this DNP quality improvement project was to improve outcomes in frail and older adult renal transplant patients through identifying risk factors, in the pre-transplant evaluation, which may lead to complications post-transplant, thereby providing opportunities for early intervention. It is expected that by facilitating a better understanding of specific risk factors contributing to poor outcomes within this population, these problems can be addressed before they have a negative impact on the patient's recovery. The 5-Factor Modified

Frailty Index has been shown in previous evaluations to be a strong predictor of post-operative complications, and is a credible tool for clinical use (Subramaniam et al., 2017). By using this standardized tool, characteristics which may potentially lead to poor outcomes can be mediated in the pre-transplant or early post-transplant periods before they evolve into an issue complicating recovery.

### **PICOT Question**

In frail and older adult renal transplant patients (P), how does the use of a standardized screening tool in the pre-transplant or immediate post-transplant period (I) compared with no standardized tool (C) affect readmission rates (O) within 3 months post transplantation (T)?

### **Needs Assessment**

#### ***Objective***

There is significant evidence that shows that by identifying risk factors in frail and older adults pre-transplant, measures can be instituted to promote opportunities for improved outcomes post renal transplant. The 5-Factor Modified Frailty Index will be evaluated to determine its value in identifying characteristics unique to the frail and older adult population in the pre-renal transplant period that may contribute to increased 30-day readmission rates post-renal transplant. The objective of the Needs Assessment was to identify and engage the target group of participants as well as an identified key influencer to further assess the need for this project within the population of patients in the transplant program and to determine factors related to increasing support for its success.

#### ***Participants***

The participants conducted in the Needs Assessment included a target group of five individuals who practice at the transplant center where the project will be implemented and who

possess the professional medical qualifications required to identify gaps in care and barriers between referral of patients for renal transplantation, the patient's ability to complete the pre-evaluation process, through the determination if each patient qualifies to be placed on the renal transplant wait list. This included four Transplant Nephrologists and one Transplant Nurse Practitioner, all of whom were experienced providers and shared the responsibility of evaluating and presenting every patient referred for renal transplant to the committee for approval. This group of individuals practiced at the transplant center where the project will be implemented and were the professionals who would be knowledgeable of the differences between current practice and gaps in care, and were able to address if this topic is a relevant area for research. Additionally, an individual in transplant administration responsible for managing the provider practice aspect of the transplant program, was identified as a key influencer and was interviewed.

### ***Methods***

The Needs Assessment included target group interviews and an additional key informant interview in the collection of required information for assessing and making recommendations in the care of frail and older adult renal transplant patients. Information related to the project was presented and a guided question interview was utilized to obtain feedback and understanding of attitudes and experiences that might influence the projects implementation. The 5 target population participants were interviewed. They were selected based on their professional role in working with this population of patients. The target population included four Transplant Nephrologist, including the medical director and one Transplant Nurse Practitioner. A key informant from the administrative side of the transplant team was also interviewed. This individual was chosen based on their role as a decision maker and leader within the transplant program. A convenience sample was utilized. This is a non-probability sampling method, and is

the most applicable and widely used method in clinical research (Elfil et al., 2017). See Appendix 1 for the target population questionnaire and Appendix 2 for the key informant questionnaire. The interviews were held in a conference room setting. The topics included provider concerns related to the frail and older adult renal transplant patient and their attitudes related to gaps in present care. Specific findings showed 100% of the providers noted that there is a definite gap in the evaluation process, particularly related to frailty. All of those interviewed were open and receptive to an improved evaluation tool and methodology applicable to individualized care for this group of patients.

### ***Findings***

On question one for the target group, three of the providers noted that they each evaluate between 10-15 patients within a year who could be considered frail or elderly and who also experience worse outcomes than their younger counterparts. The remaining providers noted they recall likely evaluating 6-10 of this population of patients. This population as noted in the findings of the Needs Assessment may represent a significant number of individuals evaluated with frailty characteristic in proportion to the number of renal transplantations performed at the transplant center. In 2019 there were 116 kidney alone transplantations and in 2020 there were 127 kidney alone transplantations performed (SRTR, 2021). On the question of the need for further measures to improve outcomes in this population each provider said that more measures should be taken and new governmental kidney transplant initiatives were cited to explain that this is a growing population being seen for kidney transplant evaluation. Related to question three, addressing the identification of these patients in pre-transplant process, all providers agreed that they are sometimes identified, but went on to say that there is no additional process

or intervention in place for effective follow-up and they all felt the center would be open to change if it could be easily implemented and could show improved outcomes in this population.

In regard to the first question presented to the key influencer it was noted that there are often discussions with providers regarding outcomes, though this population is not generally specifically addressed. It was noted that the provider to the target population questionnaire did raise important questions and she felt the program would be open to moving forward with the implementation of an evaluation process for frail and elderly potential transplant recipients in the pre-transplant evaluation period.

### **Aim and Objectives**

The focus of this project is to improve outcomes for the frail and older adult post-renal transplant patient and to determine the effectiveness of the 5-Factor Modified Frailty Index to predict early readmission post-renal transplant.

Specific Aim: Determine the effectiveness of the 5-Factor Modified Frailty Index to predict early readmission rates in older adult patients within 30 days after renal transplantation.

Objective 1: 100% of renal transplant patients who received a renal transplant within one year prior to project implementation will be evaluated for frailty using the 5-Factor Modified Frailty Index.

Objective 2: A process for evaluation of frailty pre-renal transplant will be determined using the 5-Factor Modified Frailty Index.

Objective 3: Patients at risk for early hospital readmission will be identified using the 5-Factor Modified Frailty Index.

## **Review of Literature**

The literature search was performed using a variety of scholarly databases and with the assistance of the Research Librarian from the University of Arkansas Library Center. Combinations of key words were used that related to patients undergoing kidney transplantation, and the search was then narrowed to include the diagnosis of frailty and terms suggestive of older adults. The terms searched included “kidney,” “transplant,” “frailty,” “evaluation,” “elderly,” “postoperative,” “readmission” and “comorbidity”. Additional searches included topics related to measuring frailty, the impact of comorbid conditions on kidney transplant outcomes, readmission rates in renal transplant patients, and information related to the use of scales to measure frailty. The search was limited to the years between 2016 – 2021 to ensure the most recent and relevant information is utilized, except in the case of older, landmark studies, and these are identified as such. Databases included in the search were PubMed, MEDLINE Complete, and CINAHL Complete, which yielded the most relevant articles on the topic. Only scholarly, peer-reviewed articles were included, and editorials or research not directly related to the topic were excluded. The search yielded 27 articles which were used for this literature review.

### ***Ageing and Frailty***

Age related decline can be a burden for individuals, families, and society as a whole. Healthy ageing is a concept that should be applied across the spectrum of healthcare to prevent age associated disease which leads to cognitive and physical decline. Frailty is noted to be a state of high vulnerability, and is classified as one of the most significant risk factors for mortality in older adults resulting in greater detrimental health outcomes when compared to individuals who are not frail (Palliyaguru et al., 2019). As healthcare providers it is critical that we continue to

identify and determine ways to effectively treat vulnerable individuals and ensure that they are able to benefit from medical resources that promote improved health as well as quality of life, and that they are not denied these opportunities. Kidney transplant is a treatment option for end stage renal disease that offers restoration of kidney function, but can lead to postoperative complications for the frail and older adult recipient that may hinder their ability to enjoy the full health benefits that transplantation can provide. The trend of a gradual increase in the age of kidney transplant candidates on the transplant wait list over the last 10 years continued, with candidates age 50-64 years old remaining the largest age-group on the transplant waitlist, and the proportion of candidates 65 years of age and older has also continued to rise (Hart et al., 2021). In order to more fully meet the needs of this vulnerable population, it is important to find an effective approach in identifying frailty among older individuals and address those characteristics that lead to negative health outcomes.

### ***Impact of Frailty on Kidney Transplant Outcomes***

Ageing and frailty are issues that can affect an individual's ability to successfully navigate the renal transplant process including referral, approval, and recovery. Frailty is a condition that is known to be a predictor of adverse outcomes among renal transplant recipients (Chu et al., 2019). Studies indicate that frail elderly post renal transplant patients have a greater risk for specific physiologic responses that may contribute to prolonged and complicated recoveries. A state of increased inflammation and decreased immune function are characteristics of the frail patient's phenotype and contribute to delayed recovery and increased risk for postoperative complications (Schopmeyer et al., 2019). In addition to the potential for challenging recovery periods, individuals who have been identified as having components of frailty have a greater risk of mortality after transplant. Research has recognized that there is a



61% higher risk of early hospital readmissions for frail patients when compared to their non-frail counterparts as well as a greater than twofold increased risk of mortality (Schopmeyer et al., 2019).

Decisions related to increased age and qualifications for kidney transplant will continue to be challenged as the population becomes older and the demand grows. While the number of older patients listed for kidney transplant continues to increase as the United States population continues to live longer, studies have shown that older recipients have worse graft and overall health outcomes than younger recipients (Mandelbrot et al., 2017). Few studies have addressed the growing concern of how to evaluate the frail and older adult kidney transplant candidate and consensus is needed among transplant professionals to address this issue.

### ***Identifying Frailty in the Renal Transplant Recipient***

Increasing evidence for the negative effects of frailty on surgical outcomes is contributing to the evolution of risk stratification science across surgical specialties (Gondal et al., 2019). With this in mind, risk stratification and prediction related to poor outcomes based on frailty could be relevant to the pre-kidney transplant evaluation process as well. Despite the fact that frailty is a modifiable risk factor, it is associated with a decreased likelihood of being approved for placement on the transplant wait list, and a lower rate of receiving a transplant (Haugen et al., 2019). It has been shown that relatively few of the U.S transplant programs report standardized protocols related to age cut-offs for listing, or for distinguishing between physiological and chronological age (Mandelbrot et al., 2017). By analyzing how to predict post kidney transplant complications, using standardized tools that integrate frailty scores, can help to provide evidence for decision-making related to the medical management of this group of patients before and after transplant.

Frailty assessment can further the identification of individuals who are at higher risk for return to surgery or discharge to a skilled care facility allowing for better planning, management of resources, and engagement of patient support systems (Panayi et al., 2019). Incorporating a standard frailty evaluation into the risk stratification strategies in the pre-transplant as well as post-transplant periods enables the transplant team to create a care plan that anticipates the patient's lower ability to cope with the stress of surgery. Studies show that the evaluation of elderly patients for potential transplant varies widely between transplant programs in the United States (Mandelbrot et al., 2017). The establishment of a standardized process for evaluation of the frail and older adult renal transplant candidate based on research and reliable evidence would be a step towards recognizing and addressing the unique needs of this population.

Historically age has been used to predict the risk of poor surgical outcomes; however, the concept of frailty is an additional way to explain the discrepancies that may exist between a patient's chronological and physiological age (Panayi et al., 2019). The measurement of frailty provides an additional dimension to age alone, and advances the transplant team's capacity to quantify the clinical prognosis of a likely or potential outcome. Frailty has been shown to be the most influential factor in predicting postoperative complications in the renal transplant recipient when compared to the Charleston Comorbidity Indicator or transplantation type; however, evaluating frailty is a complex process consisting of multiple components and domains (Schopmeyer et al., 2019).

To better understand the role of frailty in renal transplantation it is necessary to develop a means to assess and easily describe the effects it has had on an individual's overall health and physiologic reserve. The 5-Factor Modified Frailty Index (mFI-5) has recently been developed to overcome barriers of other health measures that may be lengthy and have limited clinical utility

(Khalafallah et al., 2020). The mFI-5 was tested in 6,494 patients with the mean age of 65 years, undergoing surgical intervention for distal radius fractures, and compared with patients who had a mFI-5 score of 0, those patient with a score of 2 or greater were 2.5 times as likely to incur a postoperative complication (1.7% vs 7.4%), and the study concluded that a state of frailty is a highly predictive of postoperative complications (Wilson, et al., 2018). This frailty index may be an appropriate tool to use in identifying individuals who may benefit from interventions prior to transplant or during the early recovery period, and would help in determining long-term post-transplant care needs.

### ***The 5-Factor Modified Frailty Index***

Though there are a number of assessment tools to identify, diagnose, or measure the severity of frailty, many have not been proven valid, reliable, accurate, and able to show good predictive ability; nevertheless, a consensus has risen around two operational approaches which are the frailty phenotype and the deficit accumulation approach (Martin et al., 2020). For purposes of this DNP project the deficit accumulation approach, using a frailty index, will be used to identify characteristics of frailty which may negatively impact recovery post-renal transplant resulting in early hospital readmission. While the frailty phenotype focuses on specific parameters that represent evidence of clinically relevant reduced physiological function, the deficit accumulation approach operationalizes frailty as a collection of symptoms, health behaviors, clinical signs, diagnoses, and functional limitations contributing to poorer health status (Martin et al., 2020). In a study of 21,426 patients aged 60 years and older undergoing primary bariatric procedures the prevalence of frailty defined by the modified frailty index was 44.4%, and frail status was independently associated with higher odds of 30-day adverse events (Gondal et al., 2019).

The modified frailty index (mFI-11), which is an 11 variable assessment tool, has been used within the National Surgical Quality Improvement Program (NSQIP) by the American College of Surgeons to integrate the concept of frailty, and has been proven to adequately reflect frailty to predict mortality and morbidity (Subramaniam et al., 2020). In this DNP project a concise version of the mFI-11, referred to as the 5-Factor Modified Frailty Index (mFI-5), was utilized. The mFI-5 has been proven to be an appropriate replacement for the mFI-11 (Subramaniam et al., 2020). In addition to the data contained in the mFI-5 tool, demographic data was also collected including type of transplant (deceased or living donor transplant), age, gender, body mass index (BMI), type of dialysis or pre-emptive status, and time from referral for transplant to listing for transplant. Please see Appendix F for the data collection tool utilized in this project. The 5 variables that make up the mFI-5 are functional status, diabetes, history of chronic obstructive pulmonary disease, congestive heart failure, and hypertension requiring medication (Subramaniam et al., 2020).

### ***The Need for Further Research***

Further research studies are needed to determine how age and comorbidities affect kidney transplant outcomes to determine older adults that are appropriate for a kidney transplant and how their care should be managed. Findings compiled through surveys from 59 transplant centers across the U.S. show that there are variable practice patterns in determining the impact of cognitive or functional impairments, the difficult challenge of estimating physiological age, and the need for formal measurements of frailty (Mandelbrot et al., 2017). This highlights the need for research to define and standardize a measurement of functional characteristics and disabilities common in this population. Establishing a foundation of understanding related to the needs of this population creates an environment of greater acceptance and may lead to increased

accessibility for individuals who may have otherwise been labeled as too high risk to be considered for transplant. Successful renal transplantation has the potential to improve the longevity and quality of life for individuals with end stage renal disease and also has an impact on society as a whole. Improving the care of this vulnerable patient population also reduces the burden on the healthcare system related to cost and resource utilization when there are readmissions, complications that have to be managed, and the loss of an allograft that could have provided life-saving benefits. Enhancing well-being and quality of life profoundly affects the health goals of a society (Palliyaguru et al., 2019). By focusing on improving the outcomes for frail and older adult kidney transplant patients through early identification of their unique needs and the development of a risk stratification process to establish an appropriate plan of care, they will have a greater likelihood of experiencing a healthier life.

### **Theoretical Framework**

Survival has been the focus of aging research for many years; however, interest is increasing towards integrating health indices in the exploration of age-related outcomes, with frailty being one measure known to correlate strongly with the human aging process (Palliyaguru et al., 2019). Addressing complications of aging is an important aspect of kidney transplantation in order to minimize the social, medical, and economic burdens that a slow or problematic recovery can create. Previous studies indicate that a state of frailty is highly predictive of postoperative complications, including readmission rates and increased length of stay; however, data suggests that a simple frailty evaluation can help inform surgical decision making (Wilson et al., 2018). Relevant practice issues addressed in this quality improvement initiative include the application of the 5-Item Modified Frailty Index to evaluate its effectiveness in predicting early readmission rates in the frail and older adult renal transplant patient providing opportunity to

implement interventions to improve health outcomes. The theoretical framework chosen to guide this project was Donabedian's model for assessment of healthcare quality.

The Donabedian conceptual framework uses the triad of structure, process, and outcome to evaluate the quality of health care; and this triad, along with the addition of seven pillars of quality also described within the model, have been well tested and proven to inform efforts to improve health care (Ayanian et al., 2016). This theoretical approach is aimed at measuring and improving healthcare quality, and is a model that can be applied when evaluating frailty in the post-transplantation setting where the ultimate goal is to improve outcomes and promote quality care in this population. Frailty has been clinically described as a state of slower function and impaired ability to recover from stressors such as infection, injury, surgery, or psychological distress (Martin et al., 2020). Determining the value of the 5-Factor Modified Frailty Index for predicting early post-renal transplant readmission rates in this population can be accomplished through the concepts of structure, process, and outcome found in Donabedian's model of quality improvement, to develop an effective approach to risk stratification and preventative interventions.

### ***Donabedian's Model for Health Care Quality***

Avedis Donabedian was a well-established expert in the field of public health when he was commissioned to review research on quality assessment by the Health Services Research Section of the United States Public Health Service in 1965, resulting in the article "Evaluating the Quality of Medical Care" which became central to his work on the theory and practice of quality assurance and health services research (Ayanian et al., 2016). The structure of care needed to meet the unique needs of patients undergoing kidney transplantation requires high quality, evidence-based evaluation and interventions. Identifying risk factors such as frailty can

have a positive impact on patient care and the economic well-being of the hospital and transplant program as well. The components identified in this theory provide a conceptual foundation for quality assessment and are an appropriate guide to evaluate the impact of frailty on hospital readmissions in patients who have undergone renal transplantation. Donabedian's model begins with three categories applicable in the evaluation of quality of health care, which he defined as "structure" being the settings and qualifications of providers and administrative systems through which care takes place; "process" as the components of care delivered; and "outcome" as recovery, restoration of function and survival (Ayanian et al., 2016). The seven pillars of quality are identified as efficacy, effectiveness, efficiency, optimality, acceptability, legitimacy, and equity (Donabedian, 1990). The attributes defined in these pillars help to provide a basis to begin identifying gaps in care, such as unidentified risk factors, and can ultimately lead to effective processes of care.

### ***Structure***

The Donabedian theory defines structure as the settings and qualifications of providers and administrative systems through which care takes place (Ayanian et al., 2016). The hospital and the trained specialist within the transplant program are the basic structure for provision of care for renal transplant patients. The use of a frailty index provides an additional mechanism to evaluate vulnerability within this population. Donabedian emphasized the need for valid measures of structure that could be linked to outcomes (Ayanian et al., 2016). Comorbidities and functional limitations associated with frailty can create a profound impact on recovery and quality of life, particularly in the post-operative period. Studies have shown that the 5-Item Modified Frailty Index is an effective risk assessment tool to guide preoperative counseling and surgical decision-making, and note that additional studies are needed to further validate its use

and analyze other specific complications not yet studied (Wilson et al., 2018). This brief survey can be easily applied in the practice setting and, through the structure-process-outcome model, provide important information for individualized post-transplant care planning.

### ***Process***

Donabedian defines process as the components of care delivered, and in this category, highlights the importance of representative samples and clear measurement standards (Ayanian et al., 2016). In the development of a process for evaluating quality in the post renal transplant environment, reliable measures of quality should be validated and the steps easily duplicated within the patient population. The process of evaluation using the 5-Item Modified Frailty Index has been used previously to successfully predict complications in various other subspecialties and its use has been validated against the 11-Item Modified Frailty Index score (Wilson et al., 2018). The process approach to assessment is useful when evaluating multiple elements and when the goal is to make the task precise, complete, and replicable. Within the framework of Donabedian's three-part approach to assessment, the healthcare providers and the hospital are described as the foundation for the ladder that progresses toward the goal of what is defined as quality care (Donabedian, 1997). The elements of the frailty assessment tool can be used to guide the process of improving measurement standards for a patient population more vulnerable to poor outcomes.

### ***Outcome***

The component referred to as outcome is defined by Donabedian as recovery, restoration of function, and survival (Ayanian et al., 2016). Within the context of this theoretical framework, an interrelationship between process and outcome is described. Both process and outcomes can be measured, validated and compared since the validity of one reflects on the other (Donabedian,



1997). The process of using a frailty assessment tool such as the 5-Item Modified Frailty Index can be evaluated independently for quality as well as the outcome data that is observed as part of its integration with the structure and process components of the theory's triad. Research has noted that frailty assessment is not simply a way to capture a list of comorbidities, and the Modified Frailty Index has the capacity to provide a more general physical portrayal by incorporating social, functional, and cognitive factors along with the comorbidities (Panayi et al., 2019). Standardized measures can be useful in connecting structure and process to improve outcomes. The flow of information in this quality assessment conceptual model correlates with the potentially broad scope that the 5-Item Modified Frailty Index has to identify risk for complication within this population of patients.

### ***Seven Pillars of Quality***

In his landmark writing Donabedian (1990), notes that there are seven attributes of health care that define quality:

- Efficacy – the ability of care, at its best, to improve health;
- Effectiveness – the degree to which attainable health improvements are realized;
- Efficiency – the ability to obtain the greatest health improvement at the lowest cost;
- Optimality – the most advantageous balancing of costs and benefits;
- Acceptability – conformity to patient preferences regarding accessibility, the patient-practitioner relation, the amenities, the effects of care and the cost of care;
- Legitimacy – conformity to social preferences concerning all of the above; and,
- Equity – fairness in the distribution of care and its effects on health.

These pillars of quality serve to enhance the understanding of the conceptual model and its application to the healthcare quality improvement process. The concepts in the seven pillars can

be logically applied to this DNP quality improvement project through the effective use of the mIF-5 in identifying obstacles to equity in better health outcomes and improved resource utilization. The Donabedian approach to quality assessment integrates the concepts of good structure to increase the likelihood of good process, and good process increasing the likelihood of good outcomes (Donabedian, 1997).

### ***Aday's Theory of Vulnerability***

In addition to Donabedian's Model for Healthcare Quality, Aday's Theory of Vulnerability was also utilized as a framework to guide the project's development. Aday's Theory of Vulnerability focuses on relative risk in vulnerable populations, noting that these individuals are at higher risk of poor physical, psychological, and/or social health, with that risk of harm or neglect being multiplied in those who are chronically ill (Aday, 1994). By integrating the concepts of risk related to chronic illness there is an additional perspective to the impact that frailty may place on an already vulnerable group of individuals. The concept of risk within this theoretical framework suggests that there are interrelationships among resource availability, including socioeconomic and environmental, relative risk associated with the likelihood of exposure to risk factors, and health status, defined by disease prevalence, morbidity, and mortality rates (Havrilla, 2017). Evaluating frailty within the framework of relative risk for poor health outcomes helped to establish the vulnerability of this population and the need for further consideration of their unique needs.

## **Methodology**

### ***Project Design***

Utilizing the 5-Factor Modified Frailty Index is a proactive approach to patient evaluation prior to renal transplantation to identify characteristics of frailty that may predict

complications leading to increased 30-day readmission rates. This project took place in the inpatient transplant unit and outpatient transplant clinic at an academic hospital in Tennessee. A retrospective cohort study was conducted among adult patients who underwent renal transplantation surgery within one year prior to implementation of the project.

### ***Project Description***

The implemented DNP project identified the relationship of frailty to 30-day readmissions among adult post-renal transplant patients. The approach of this project was an observational research design, retrospective cohort study, utilizing the 5-Item Modified Frailty Index comparing the outcomes of patients meeting the frailty criteria with those individuals not meeting the criteria. The outcomes measured included mFI-5 score and 30-day readmissions,

### ***Setting***

The setting for this quality improvement project was an urban academic hospital in Tennessee. This is a 617 acute care bed, tertiary care, and referral center, and is the home to a large transplant institute specializing in solid organ transplantation of the kidney, liver, and pancreas (MUH, 2021). The outpatient transplant clinic was the second setting utilized for this project. The outpatient clinic is also a part of this urban academic facility located in Tennessee. According to the Scientific Registry of Transplant Recipients (2021), this transplant program performed 109 renal transplants between July 2019 and June 2020, and the outpatient clinic follows over 800 patients. The program consists of three transplant nephrologists, three transplant hepatologists, and six transplant surgeons.

### ***Study Participants and Interventions***

Study interventions consisted of medical record reviews of all adult patients who had undergone deceased donor or living donor kidney transplantation between December 2020 and

December 2021 prior to the project implementation, with the exception of patients whose kidney transplantation included a simultaneous pancreas or liver transplantation. Demographics including age, gender, race, body mass index (BMI), type of dialysis, time on dialysis, time between referral for transplant and listing for transplant, and date of transplantation were noted along with 30-day post transplantation readmission status. The 5-Item Modified Frailty Index was utilized to score frailty on each of these individuals. Components of this index include history of diabetes mellitus, congestive heart failure within 30 days before surgery, hypertension requiring medications, lung problems (COPD, pneumonia), and functional health status before surgery (Wilson et al., 2018). Medical records were reviewed to identify factors related to the components of the mFI-5 in patients who have experienced an early readmission within 30 days post-renal transplantation and those who have not.

**Pre-Implementation Phase.** Patient information, including names and records of individuals who have undergone renal transplantation at the transplant institute over the previous one year, were obtained to establish the database. Identifiers were used in place of names. Charts meeting the exclusion criteria were removed from the database. An appropriate data collection tool was developed, including all of the variables in the mFI-5 that was assessed. Each one of the components within the mFI-5 included specific criteria for scoring. Preliminary chart reviews were conducted for the previous three months with trends in missing data or problems encountered were determined and addressed prior to continuing with the data collection. Meetings were held with the key stakeholders to review and approve the components of the data collection tool prior to the implementation of this DNP project. The data collection tool was designed with components that reflected the similarities and differences within the identified post renal transplant population, as well as the aim and objectives of the project. Arrangements were

made to meet with an academic institution statistical graduate student to help with formulating statistical analysis from the data collected through the chart review to compile the results of the project.

**Implementation Phase.** The chart analysis began following IRB approval on 12-01-2021 with demographic data and progressed to the frailty index components, moving forward to the post-transplant outcomes. Data was assessed weekly to ensure the data collection tool is appropriate and that the project objectives were being met. Through the use of Donabedian's framework for healthcare quality, data was evaluated regularly for any discrepancies and adjustments initiated, to keep the project focused on the research objectives and moving in the right direction.

**Post-Implementation Phase.** The information that was gathered by using the mFI-5 scoring tool to analyze and evaluate if the components of the 5-Item Modified Frailty Index consistently identified characteristics that contribute to increased 30-day readmission rates among post-renal transplant patients. Data was compiled comparing the mFI-5 scores with the 30-day post renal transplant readmissions identified. The results of the project were provided to the facility's key stakeholders, the inpatient transplant unit, the outpatient transplant clinic, and the Eleanor Mann School of Nursing.

### ***Study Measures***

**Conceptual Definitions.** The conceptual definition of the term *readmission* refers to the subsequent admission that occurs within a given period of days after an initial discharge. The conceptual definition of the term *frailty* refers to a vulnerable state of health (Chu et al., 2019).

**Operational Definitions.** The operational definition of the term *5-Item Modified Frailty Index* is how frailty was measured and operationally defined in its use as a predictor of

admission to the hospital within 30 days after renal transplantation. *Readmissions* were measured by conducting chart reviews to determine the number of patients who are admitted to the hospital within 30 days after their kidney transplantation. *Post-renal transplant* and *post kidney transplant* referred to the period following receipt of a living or deceased donor kidney transplantation.

**Outcome Measures.** Recovery, restoration of function, and survival are patient outcomes that are indicators of care quality (Donabedian, 2005). The outcome measures for this quality improvement project included the evaluation of the 5-Item Modified Frailty Index as a predictor of early readmission after post-renal transplantation in order to identify the need for proactive interventions in this population. A retrospective chart review was performed to gather data on the number of patients with readmissions within thirty days post-discharge and the identification of the diagnoses prompting the readmission. Readmissions, frailty components identified, and the related 5-factor index score were entered into the codebook where the data results were recorded. Outcome measures included rates of admission in the identified frailty group compared to the non-frail group and the percentages of patients identified as frail using the mFI-5 tool, and percentages of patient identified for each of the components of the mFI-5 tool.

**Process Measures.** The evaluation of the 5-Item Frailty Index is the primary process measure in this project and included 100% of patients who have received a living donor or deceased donor renal transplant within the year evaluation period. Simultaneous pancreas and kidney and simultaneous liver kidney transplantations were excluded. The presence of the components of the mFI-5 were determined along with readmission rates to determine if the mFI-5 score is a statistically significant reflection of an increased early readmission rate.

**Balancing Measures.** Balancing measures for this DNP project include proactive factors

that may already be in place that can impact readmission rates such as emergency room visits, use of outpatient resources (home health care or the transplant outpatient infusion center) to treat symptoms in order to delay or prevent readmission.

### ***Benefits/Risks***

Benefits of this DNP project included the identification of characteristics in the frail post-renal transplant population which may lead to poor outcomes. By identifying factors which may lead to early hospitalization post-transplant, an evidence-based practice intervention can be established to address this gap in care. This will add to the body of knowledge related to post-operative preventative measures and common complications, and facilitate further research of this vulnerable population. Patient's medical records were protected and identifiers used in place of names. There was minimal risk of potential loss of the patient's privacy and confidentiality through data production and collection and all needed precautions to reduce the loss of privacy and confidentiality was taken.

### ***Subject Recruitment***

Retrospective chart review was utilized to address the project question, including electronic databases, results from diagnostic tests, and notes from providers and healthcare staff members. There was not subject recruitment and enrollment required for this project.

### ***Consent Procedures***

This DNP project utilized a retrospective design and no study participants were enrolled. Provision for the respect and confidentiality of patient information was ensured through the use and protection of identifiers within the data collection instrument. Institutional Review Board approval was obtained for ethics consideration and oversight.

### ***Subject Costs and Compensation***

There was no cost or compensation for data collected in the project.

### **Evaluation Plan**

#### ***Data Maintenance and Security***

Information regarding the pre-transplantation frailty status of patients who had undergone kidney transplantation was collected using the hospital's Cerner electronic healthcare record database system. Names, medical record numbers (MRN), demographic data, and frailty index score of those individuals were collected and stored on the IRB approved data collection tool kept on the password protected private computer in a locked office within the hospital. Access was not granted to anyone without explicit knowledge and permission. The collected information included patient names and MRN to ensure proper identification of the patient with the appropriate data and frailty score. This was the only information retrieved from the medical healthcare record, no other personal information was obtained.

Data collected included:

- Socio-demographic information includes: gender, age, ethnicity, body mass index
- Time on dialysis pre-transplantation and type of dialysis
- Time between referral for transplant and approval for transplant
- Components of the 5-Item Modified Frailty Index including history of diabetes mellitus, congestive heart failure within 30 days prior to surgery, hypertension requiring medication, lung problems (COPD, Pneumonia), and functional health status before surgery
- Readmissions within 30 days after renal transplantation

#### ***Data Analysis***



Project data was analyzed to determine efficiency and success of the 5-Factor Modified Frailty Index to predict the rate of 30-day readmission among post renal transplant patients. A retrospective chart review (RCR) was performed and Electronic Medical Records (EMR) were evaluated from both the pre-transplantation and post-transplantation timeframes. The review was intended to determine if the 5-Factor Modified Frailty Index (MFI-5) could be used to identify characteristics of this population which may contribute to the need for readmission within 30 days after transplantation. The MFI-5 has been proven as an effective predictor of post-operative complication and has been shown to have credibility for use to study frailty and for clinical assessment (Subramaniam et al., 2020). Statistical methods were used to analyze the data received from the chart reviews. In selecting the appropriate statistical method, consideration should be given to the aim and objective of the study, the type and distribution of the data that is used, and the nature of the observations, whether they are paired or unpaired (Mishra et al., 2019). Analysis was done using IBM Statistical Package for the Social Sciences (SPSS). Descriptive and inferential statistics were used to display the variables of each individual. Descriptive statistics is a method used to summarize data using the indicators of mean, median, and standard deviation (Mishra et al., 2019). A logistic regression model was utilized to measure correlation between the mFI-5 score and 30-day readmissions rate. In addition to including the outcome variable, the logistic regression model includes predictor variables thought to be associated with the outcome variable (Knapp, 2018).

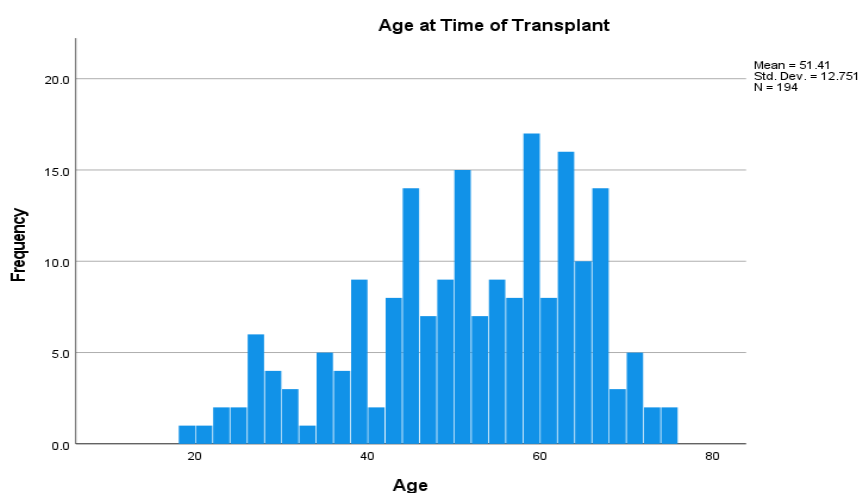
### ***Outcome Measures***

**Descriptive Statistics.** The statistical analysis for the project included descriptive statistics. Measured areas on the MFI-5 included, history of diabetes mellitus, congestive heart failure (new diagnosis or exacerbation of chronic congestive heart failure within 30 days of

surgery), hypertension requiring medication, history of chronic obstructive pulmonary disease or pneumonia, and non-independent functional status (partially or completely dependent in activities of daily living within the last 30 days prior to surgery). The index indicated either the presence or absence of the characteristic which reduced bias. The frailty score was noted as 0-5 depending on the characteristics present. In the sample population for this project, the scores noted ranged from 0-3 with no patients scoring greater than 3. Patient demographic data including type of renal transplantation (deceased or living donor), age, gender, race, BMI, type of dialysis (peritoneal or hemodialysis), and years on dialysis, were noted along with the frailty index scoring.

The population consisted of 194 individuals who had undergone renal transplantation between the timeframe of December 2020 through December 2021. Many factors that contribute to frailty in kidney transplant patients are not modifiable, such as age and gender, and kidney transplant candidates of advanced age and female sex are more likely to be frail than younger male candidates respectively (Harhay et al., 2020). The age range of patients in this project's sample was between 19 and 74 years, with a mean age of 51.4 years. See Figure 1 below.

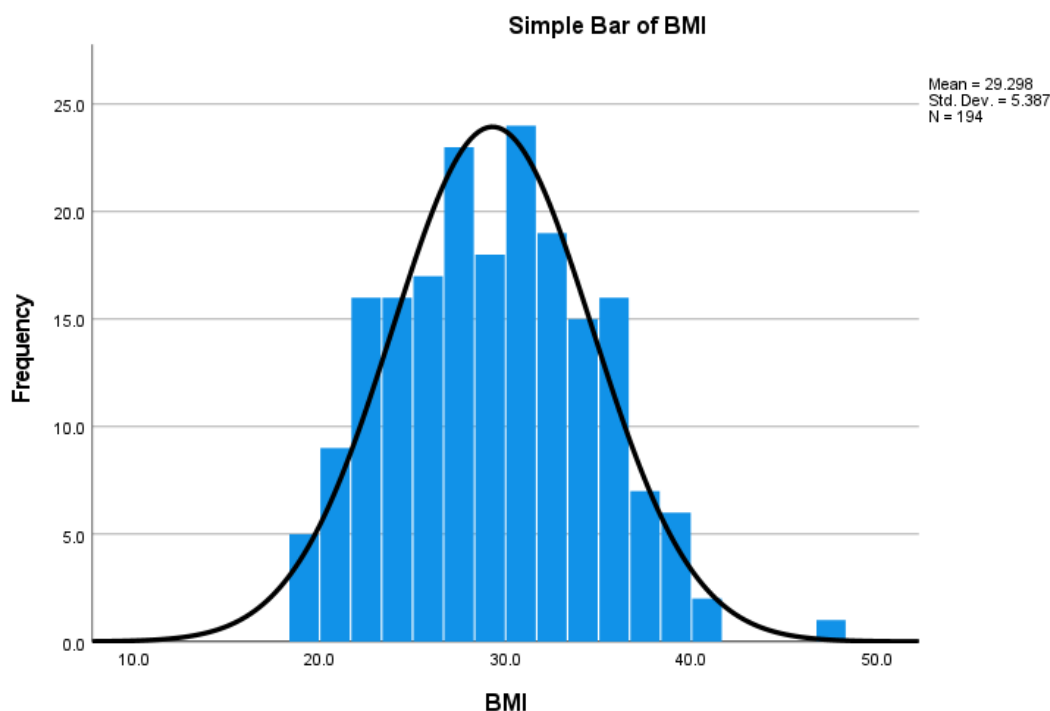
Figure 1: *Age at Time of Transplant*



General descriptive statistics for this study also included gender and race. Gender in this population was divided by 120 (62.9%) males and 74 (37.1%) females, with the majority of the sample being African-American (77.3%), and the remainder Caucasian (21.1%), and Hispanic (1.5%). Donor type was noted, with 169 (87.1%) having received deceased donor kidney transplants, and 25 (12.9%) having received living donor transplants. The mean time on dialysis prior to transplantation was 2.6 years for the entire population.

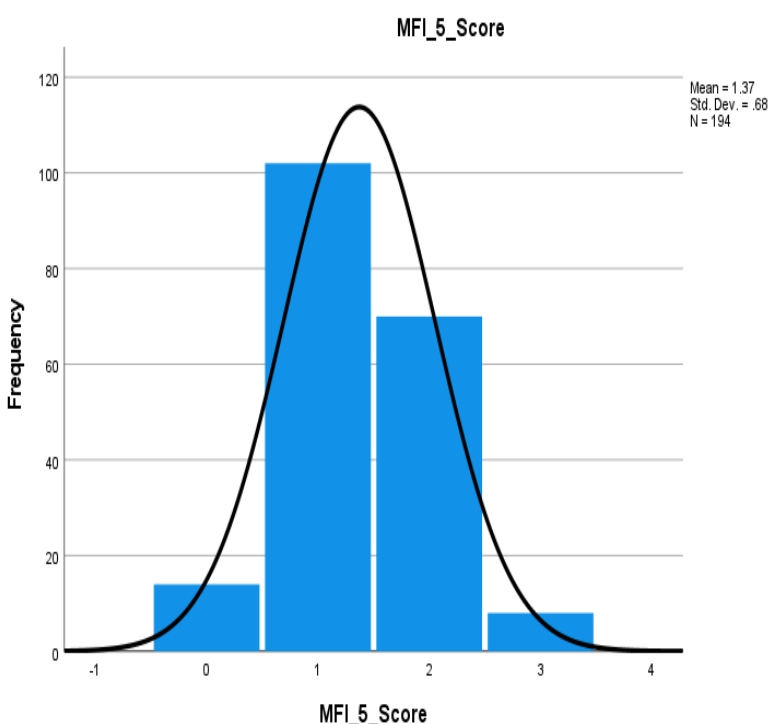
Body mass index among the sample population was also noted. Obesity has multiple implications on patients being listed for kidney transplant and on their recovery after transplant, with obese patients experiencing lower access to kidney transplant and more complications post-transplant (Quero et al., 2021) In this study sample, the mean body mass index was  $29.3 \text{ kg/m}^2$  with the lowest being  $18.6 \text{ kg/m}^2$  and the highest being  $48.0 \text{ kg/m}^2$ . See figure 2 below for BMI demographics.

Figure 2: *Body Mass Index*



**Readmission by 5-Factor Modified Frailty Score.** On the 5-Factor Modified Frailty Index, in the project sample population of 194 post-renal transplant patients, 14 patients scored 0 (7.2%) with 5 being readmitted (35.7%), 102 scored 1 (52.6%) with 26 readmitted in this group (25.5%), 70 scored 2 (36.3%) with 31 being readmitted (44.3%), and 8 scored 3 (4.1%) with 5 in this group being readmitted (62.5%). Additionally, a total of 67 (34.5%) were readmitted within 30 days after their renal transplant. See Figure 3. Comparatively, research in the United States shows a post-renal transplant 30-day readmission rate of 30.5%, with rates from 11% to 47% being reported for single centers (Famure et al., 2021).

Figure 3: *mFI-5 Score*



No missing data was observed for all variables used to calculate the mFI-5 score. Two groups within the mFI-5 scoring components, scores 2 and 3, showed readmission percentages (44.3% and 62.5% respectively), indicating that a higher mFI-5 score coincided with a higher percentage

rate of readmission. In analysis by score ranking, the lowest readmission rate was among patients with no frailty components (35.7%) and the highest readmission rate (62.5%) was noted among patients with 3 frailty components. All frailty components were significantly associated with unadjusted readmission rates. A mFI-5 score of 3 contributed most to the ability of the mFI-5 to anticipate readmission (62.5%) compared to the other scores. In this study, there were no patients at the higher end of the mFI-5 scale (total score of 4 or 5 frailty components), and a score of 3 was the highest score attained. Table 1 below shows the readmission rates based on the 5- Factor Modified Frailty Score.

Table 1: *30-Day Readmissions by mFI-5 Score*

mFI-5 Score	Number of Patients	Readmission
0	14	5 (35.7%)
1	102	26 (25.5%)
2	70	31 (44.3%)
3	8	5 (62.5%)
4	0	n/a
5	0	n/a

**Logistic Regression.** By assigning one point for each comorbidity present (diabetes, hypertension, CHF, COPD, and functionally dependent status), a logistic regression was performed to determine the effectiveness of the 5-Factor Modified Frailty Index to predict 30-day readmission post renal transplantation. The logistic regression model requires a two-category outcome variable; however, the predictor variables can be continuous or categorical, and the findings provide insights into the outcome of the investigation, and can serve as a viable predictive model to anticipate future outcomes in similar circumstances (Knapp, 2018). In SPSS,

the 30-day readmission was entered as the outcome variable and the predictor variable was the MFI-5 score.

The omnibus tests of model coefficients can indicate the strength of the model being investigated, to predict the outcome, with a  $p$  value of  $< .05$  indicating that the overall model is statistically significant (Knapp, 2018). In this study, the chi square model of fitness showed statistical significance ( $p=.013$ ), indicating that the predictors strongly predict the outcome variable. See table 2 below.

Table 2: *Omnibus Tests of Model Coefficients*

	Chi-square	df	Sig.
Step	6.196	1	.013
Block	6.196	1	.013
Model	6.196	1	.013

The most essential findings of this logistic regression are found in table 3 below, the *Variables in the Equation* table. The outcome shows that  $\exp(B)$  was greater than 1 (1.756), which was statistically significant ( $p=.015$ ); hence, this indicates for every increase in the MFI-5 score the odds of a patient experiencing a 30-day readmission increases by 75.6% (95% CI 1.117, 2.761). See table 3 below.

Table 3: *Variables in the Equation*

<b>Variables in the Equation</b>								
	<b>B</b>	<b>SE</b>	<b>Wald</b>	<b>df</b>	<b>Sig</b>	<b>Exp(B)</b>	<b>95% CI for EXP(B)</b>	
							<b>Lower</b>	<b>Upper</b>
<b>Step 1<sup>a</sup></b>								
<b>MFI_5_Score</b>	<b>.563</b>	<b>.231</b>	<b>5.956</b>	<b>1</b>	<b>.015</b>	<b>1.756</b>	<b>1.117</b>	<b>2.761</b>
<b>Constant</b>	<b>-1.433</b>	<b>.367</b>	<b>15.258</b>	<b>1</b>	<b>&lt;.001</b>	<b>.239</b>		

<sup>a</sup> Variable entered on step 1: MFI\_5\_Score

### ***Process Measures***

There is no current practice benchmark for the measurement of frailty in this transplant institute. The evaluation of the 5-Item Frailty Index as a predictor of 30-day readmission post-renal transplant was the primary process measure in this project and included 100% of patients who had received a living donor or deceased donor renal transplant between December 2020 through December 2021. The presence of the components of the mFI-5 were determined and percentages of readmission rates were provided for each score on the mFI-5 scale. It was determined that frailty as identified by the mFI-5 was associated with unplanned 30-day readmission, and has utility in the evaluation of frailty in the renal transplant patients.

### ***Balancing Measures***

Balancing measures for this DNP project reflect the possibility that when early hospital readmissions are reduced, there may be an increase in the utilization of other resources such as the emergency department, outpatient infusion center, or home health services. These were not be measured for this project, but would be important variables to include in any future

prospective study.

### ***Findings***

The outcomes of this DNP quality improvement project indicate that the mFI-5 tool has potential utility in the evaluation process of individuals seeking renal transplantation. A higher score is associated with an increase in 30-day readmission post renal transplant, primarily in the areas related to a history of diabetes mellitus, diagnosis of hypertension requiring medications, and history of COPD or pneumonia. Logistic regression showed that  $\exp(B)$  was greater than 1 (1.756), which was statistically significant ( $p=.015$ ), indicating that for every increase in the MFI-5 score the odds of a patient experiencing a 30-day readmission increases by 75.6% (95% CI 1.117, 2.761).

The information presented in this project will contribute to the broader knowledge of frailty and post-renal transplant outcomes, specifically related to readmissions. Targeting potentially modifiable aspects of frailty such as a more aggressive approach to achieving greater control of comorbidities and improving functional status in the preoperative period may serve to improve outcomes and decrease 30-day readmission rates.

### **Recommendations and Discussions**

While the results of this project may not fully justify utilizing the mFI-5 alone as a tool to measure frailty, its integration into the assessment process along with other frailty measures that are already a part of the pre-transplant evaluation such as the 6-minute walk test, grip strength, and nutritional assessment can more fully prove its benefits and usefulness. Prospective studies including interventions based on the mFI-5 results will serve to more closely evaluate its predictive strength and define its utility in planning treatment and resource utilization. Further work is needed to evaluate the posttransplant outcomes associated with early readmissions, to



highlight the role of preventable causes, and to develop effective interventions to reduce the risk of readmissions, this effort may be facilitated by the development of prediction models to identify the patients at highest risk for readmission and careful evaluation of how relevant predictors should be incorporated into statistical models to maximize predictive accuracy (Famure et al., 2021).

### ***Economic and Cost Benefits***

Kidney transplant patients have an increased risk for complications which can result in early hospital readmission. Not only does this contribute to a decreased quality of life and overall well-being for the recipient, but it also places a burden on healthcare resources, with studies showing that early hospital readmissions after kidney transplantation result in costs of approximately \$10,000 USD for each episode (Famure et al., 2021). Appraising frailty interventions to address characteristics contributing to complications, can reduce readmission rates and therefore the significant economic burden that high readmission rates have on the healthcare system.

### ***Healthcare Quality Impact***

Evaluation of quality indicators is an important way to promote efforts to continuously improve care and monitor progress. While patient and graft survival have been criticized as imprecise measures of transplant program quality, 30-day readmission rates, available nationally and attainable locally, may better reflect the efficacy of multi-disciplinary transplant care and are therefore an important benchmark for quality improvement purposes (Kim, et al., 2019). This project focused on patient characteristics that put them at risk for early readmission to provide opportunity for risk stratification and interventions that may improve healthcare outcomes.

### ***Health Policy Implications***

Currently, there are no policies or protocols for the specific evaluation of frailty in post-renal transplant recipients. Systematic review and meta-analysis of the Modified Frailty Index has shown that it is an underappreciated prognostic indicator and strongly correlates with higher risks of post-operative complications, longer hospitalizations, higher rates of readmission, need for return to surgery, higher rates of discharge to skilled care facilities, and higher mortality (Panayi et al., 2019). The implementation of this DNP quality improvement project can focus attention on the 5-Item Modified Frailty Index as a tool to identify characteristics associated with frailty, which may contribute to early readmission, in order to standardize interventions, improve outcomes, and quantify the impact of the problem to influence policy related to standard of care.

The Membership and Professional Standards Committee of the Organ Procurement and Transplantation Network has outlined recommendations from the Performance Monitoring Enhancement subcommittee for transplant program process improvement which includes waitlist mortality as a performance metric to identify programs in need of performance improvement (OPTN 2021). This policy has the potential to further impair the ability of frail individuals to be referred and listed for renal transplantation as this population may be seen as a risk for negative performance measures for the transplant center. In a prospective cohort study of frailty including 7,078 participants, it was noted that frail individuals were 38% less likely to be listed for kidney transplantation and when listed had a 1.7-fold higher risk of waitlist mortality (Haugen et al., 2019). Measuring and standardizing care in this population can help to decrease the possible negative impact of this policy on the frail and older adult population.

### **Implications for Nursing Discipline and Professional Practice**

Kidney transplantation is a serious event that includes profound psychological, relational, and social changes for individuals and their families (De Pasquale et al., 2020). Nurses bring a

wholistic approach and a unique perspective to research, and this is an important element in evaluating the complex renal transplantation experience. Conceptual work has been described as an important component of progress in the knowledge base of a discipline, and concept development is important in facilitating this progress in nursing science on a theoretical and conceptual level as a part of united and organized development of the discipline (Rodgers et al., 2018). Through the integration of a theoretical framework and the nursing process the results will reflect insight specific to the professional practice and approach of the nursing discipline.

Unlike age, gender, or race, frailty is a potentially modifiable risk factor for poor outcomes (Haugen et al., 2019). This provides an opportunity for further nursing investigation and research to determine evidence-based practice interventions to optimize the overall physical status of these individuals through rehabilitation efforts or enhanced care. It is crucial for clinicians to identify patients during the kidney transplantation referral and evaluation process who may benefit from pre-habilitation efforts to increase their physiologic reserve during the time that they are waiting for their kidney transplant (Haugen et al., 2019).

### ***Translation***

The ability of the mFI-5 to provide a means of improvement in the way characteristics of frailty are identified, and in predicting post-renal transplant readmissions, indicates that it may be a helpful tool to use in the pre-transplant period to determine how care may be modified to improve post-transplant outcomes. Frailty assessment with the modified frailty index can identify potentially modifiable components of frailty through pre-habilitation to optimize the patient's co-morbidities in physical, nutritional, and psychosocial domains (Wahl et al., 2017). Components of the mFI-5 can be integrated into the pre-transplant evaluation and co-morbidities more robustly monitored and treatment recommendations implemented. Additionally, the

outcomes of this project can be utilized in other disciplines to enhance care and improve the evaluation of frail patients.

### ***Sustainability***

Support from hospital administration is an important component to the sustainability of any new program or evaluation tool. The administration at this facility is supportive of this project and see its potential to identify causes of the early readmission of post-renal transplant patients and how this can contribute to finding solutions to improve outcomes. Project results have been provided to the staff to emphasize the importance of addressing the unique needs of this population. An additional recommendation for sustainability includes a future prospective study comparing effectiveness of interventions in this population to improve outcomes.

### ***Dissemination***

When undertaking a research project, knowledge of how the results may potentially be used and by whom, is an important aspect in planning the ultimate process of dissemination. Stakeholders are increasingly recognizing the value in research dissemination and funders such as the National Institutes of Health and Agency for Healthcare Research Quality, now consistently ask for dissemination plans for the broader community and request stakeholder engagement in the plan development to increase the use of findings (Cunningham-Erves et al., 2019). Presenting the results to key individuals who would be interested in implementing the findings can lead to positive change. Creative means of sharing and building research information can guide novel forms of patient education, new approaches to intervention research, and improved forms of stakeholder involvement in research (Hagan et al., 2017). Lack of communication about study results to community members can lead to mistrust in medical research and the health-care community (Cunningham-Erves et al., 2019).

### ***Methods of Project Results Dissemination***

**Institution Dissemination.** The implementation of this DNP project may assist with future policies of frailty evaluation to create awareness for improving patient education during the pretransplant evaluation process and improve communication by standardization throughout the transplant process. Translation of this project's results can be implemented in other acute care settings and outpatient clinic to enhance management of adult renal transplant patients and target specific frailty related needs. Administration support is an important element to the sustainability of any project. The Transplant Institute administration are supportive of this project and its potential positive impact on addressing 30-day readmissions in the post-renal transplant patient population.

Project results will be provided to the staff to emphasize the need for continued evaluation of high-risk patients undergoing renal transplantation. The Transplant Institute has a shared interest in improving outcomes and offering solutions to early post-transplant readmissions. An in-person presentation will be provided to multidisciplinary transplant team members and the PowerPoint presentation will be available in the team meeting conference room located on the unit to aid in continued staff education.

**Healthcare Community Dissemination.** Professional reporting is another important aspect of research dissemination. Results will be disseminated virtually to the DNP committee at the University of Arkansas Eleanor Mann School of Nursing. Additionally, project results can be distributed to the *ITNS Insider* which is a publication of the International Transplant Nurses Society, *The Journal of Clinical Nursing Research*, or any nursing conference that is interested in renal transplantation care management. Future plans include to share the project's results with the International Transplant Nurses Society. Poster presentation opportunities are available for

their annual meeting in October 2022, and plan is to apply for this.

**Patient and Caregiver Education.** Measuring frailty provides opportunity to better inform patients related to risks, benefits, and recommended intervention options available to improve their overall health and post-transplant outcomes. Lack of communication about study results to community members can lead to mistrust in medical research and the health-care community (Cunningham-Erves et al., 2019). The results will be presented to transplant team members who routinely identify frailty in the renal transplant patient and provide education and counseling to these individuals, such as the transplant dieticians.

**Policy-maker Dissemination.** Research has the potential to influence US social policy, but few common strategies exist for disseminating social policy research in the United States (Ashcraft et al., 2020). While the implications of this study may not be relevant to social policy on the federal level, care for vulnerable populations such as the frail and elderly, as well as individuals with renal failure, require supportive measures on a national level. The results of this DNP project can serve to bring attention to this specific population and based on results opportunities to advocate for this group related to policy will be assessed. Research suggests that dissemination is most effective when it begins early, galvanizes support, uses champions and brokers, considers contextual factors, is timely, relevant, and accessible, and knows the players and process (Ashcraft et al., 2020).

## **Conclusion**

Frailty has been identified as multidimensional in that it affects multiple aspects of health including physical, psychological, cognitive, social, emotional, spiritual, economic, and nutritional domains; and, is associated with increasing risk of adverse outcomes (Adja et al., 2020). Additionally, research has shown that the presence of frailty at the time of transplant

presents greater than twice the risk of complications after transplant (Kobashigawa et al., 2019). By validating the 5-Factor Modified Frailty Index as an effective predictor of postoperative complications in the renal transplant population it can be established as credible for future use for clinical assessment and decision-making (Subramaniam et al., 2020).

Appropriately identifying individuals who are frail has become increasingly important in pre-transplant and post-transplant evaluation; however, receiving the diagnosis of frailty can have positive as well as negative effects for the patient. Misclassification of frailty could have large implications for access to kidney transplant as individuals who are inaccurately deemed “too old, ill, or frail” to undergo kidney transplant may be less likely to receive the benefits of transplant education or referral as a result (Harhay et al., 2020). This project focused on emphasizing an evidence-based approach to evaluating patient characteristics related to frailty that can put them at greater risk for early readmission. The outcomes of this DNP quality improvement project indicate that the mFI-5 tool can be effectively used in the evaluation process of individuals seeking renal transplantation. Logistic regression analysis showed that a higher score on the frailty index was associated with an increase in 30-day readmission post renal transplant, primarily in the areas related to a history of diabetes mellitus, diagnosis of hypertension requiring medications, and history of COPD or pneumonia. By identifying at-risk individuals, the opportunity is presented for appropriate risk stratification to assist with better resource utilization planning and proactive interventions that can increase quality of care and improve outcomes. It is also important to consider if the incorporation of frailty-based risk scores into program specific reports and criteria could reduce disincentives for transplant programs to select frail individuals who may benefit from transplant (Harhay et al., 2020). This is an area where future research could be critical to promoting progressive renal transplant care for the frail

and older adult individuals in order to provide appropriate treatment modalities to address their needs prior to transplant, so that they may have better outcomes and benefit from the improved health that receiving a renal transplant can provide.

Additionally, this project has served as an impetus to move the study of frailty in the renal transplantation population forward to future investigation through more prospective and retrospective studies in areas such as addressing frailty in the pre-transplant dialysis patient, integrating a more effective frailty model of evaluation in the pre-transplant listing period, and obesity related frailty. The outcomes of this project demonstrate the value of the mFI-5 as a useful tool to identify frailty characteristics and predict risk for readmission post-transplant. Additionally, as research has shown the strong association between frailty and adverse outcomes, frailty assessments can have implications in the monitoring and regulation of transplant program performance (Harhay et al., 2020).



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## Appendix A: Questions for Target Group

**PROVIDER SATISFACTION OF DECISION-MAKING RELATED TO PRE-TRANSPLANT EVALUATION  
OF FRAIL AND ELDERLY POTENTIAL KIDNEY TRANSPLANT RECIPIENTS**

This questionnaire is designed to measure how you feel about your involvement in decisions and communication related to the process of pre-transplant evaluation, selection, and follow-up of individuals identified as frail or elderly. During the pre-transplant evaluation period you may have had many opportunities to assess patients where concerns have arisen in regard to age related factors which may impact their abilities for self-management and overall outcome post-transplant. Consider the pre-transplant evaluations you have performed and the outcomes you have noted over the past two years when answering the questions.

1. Frequency of encountering this population in general practice: In your practice experience do you see a significance difference in outcomes in patients you consider to be frail or an older adult transplant patient?
  - a. None
  - b. 1-5 /year
  - c. 6-10 /year
  - d. Over 10/year
2. Do you feel that measures could be taken that would improve outcomes in this patient population?
  - a. Not sure
  - b. Comfortable with measures already being taken. Explain.
  - c. Yes. Explain.
3. Do you feel these patients are being identified in the pre-transplant process?
  - a. Never
  - b. Sometimes
  - c. Most of the time
  - d. Always
4. Do you feel our center would be open to change in the pre-transplant process to identify and implement interventions to specifically address this populations unique needs?
  - a. Yes – Explain
  - b. No - Explain

## Appendix B: Questions for Key Influencer

**CHALLENGES TO IMPLEMENTATION OF PROVIDER DRIVEN ASSESSMENT TOOL FOR IDENTIFYING FRAIL AND ELDERLY POTENTIAL KIDNEY TRANSPLANT RECIPIENTS**

This questionnaire is designed to measure how you feel about the transplant program's readiness to implement an additional assessment in the pre-transplant evaluation process related to the evaluation, selection, and follow-up of individuals identified as frail or elderly. During the pre-transplant evaluation period the transplant center utilizes a team approach to recipient evaluation and selection. Consider the following questions after reviewing the provider responses in the target group questionnaire.

1. How often do providers make you aware of concerns related to renal transplant outcomes?
  - a. Never
  - b. Rarely
  - c. Sometimes
  - d. Frequently
2. After reviewing the provider responses from the providers in the target group questionnaire, how ready do you think the program is to implement an additional assessment for frailty in potential kidney transplant recipients?
  - a. Not possible
  - b. Could be considered
  - c. Definitely, should be implemented
3. Please describe the challenges you foresee in implementing this intervention.





College of Education and Health Professions  
 Eleanor Mann School of Nursing  
**Appendix C: Global Aim Statement**

**Write a Theme for Improvement: Improve outcomes in frail and older adult post renal transplant patients**

**Global Aim Statement**

We aim to improve: outcome and transplant experience for renal transplant patients identified as frail and older adult.

In: The transplant institute at Methodist University Hospital in Memphis, Tennessee

The process begins with: pre-transplant evaluation.

The process ends with: 3 months after transplant.

By working on the process, we expect: to improve patient satisfaction, decrease readmissions, and improve outcomes

It is important to work on this now because: There is a clear need that exists for more studies in this population to enhance care through improving the pretransplant evaluation process to provide opportunities to optimize patients for transplant, provide more data to guide management of immunosuppression, and individualize post-transplant care (Singh et al., 2016).

Singh, P., Harn-Yue, N., & Unruh, M. (2016). Kidney transplantation among the elderly: Challenges and opportunities to improve outcomes. *Advances in Chronic Kidney Disease*, 23(1), 44-50.

**Create Flowchart**

**Specific Aim Statement**

We will: ☐ improve ☐ increase ☒ decrease

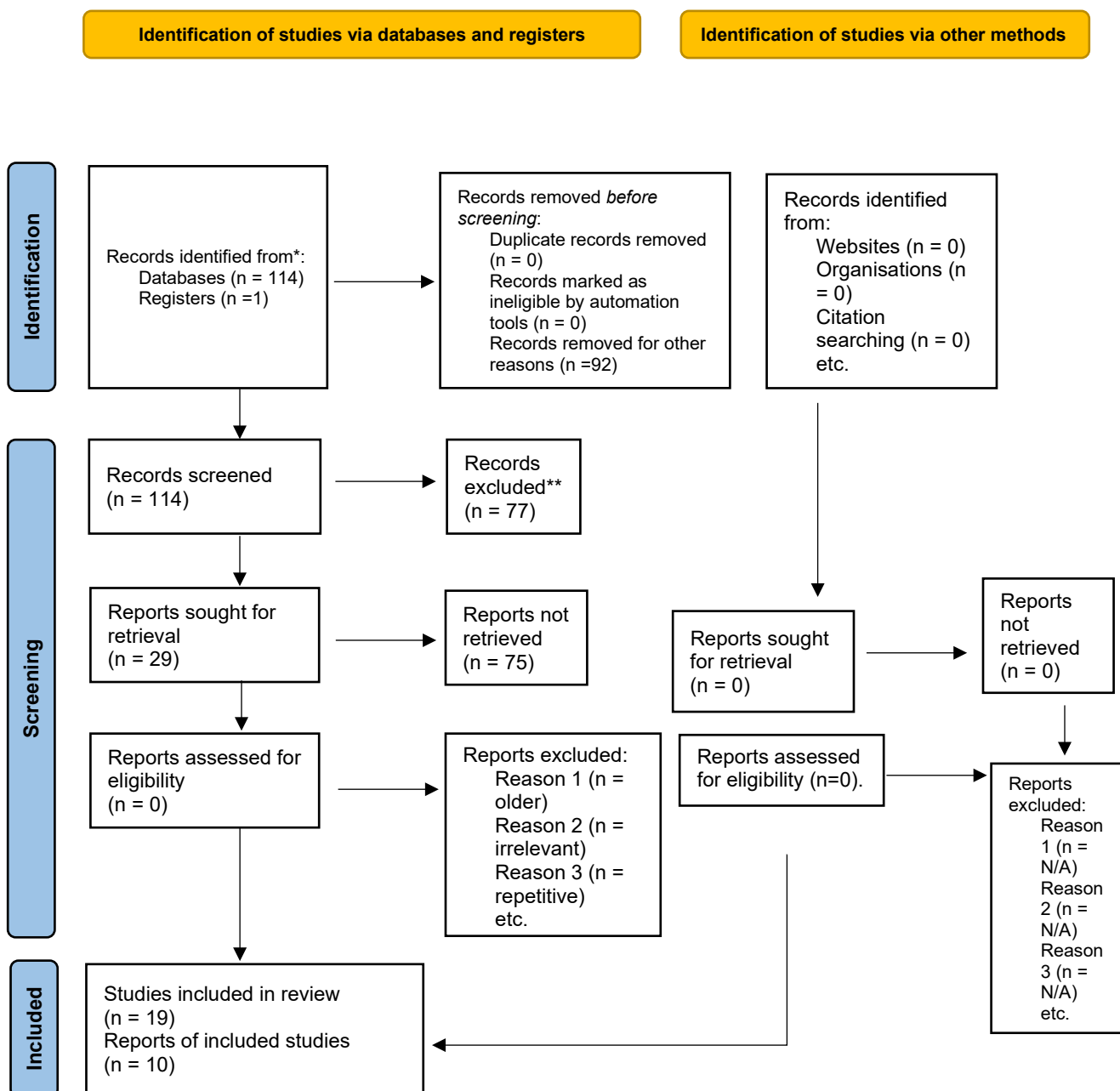
The: ☐ quality of x number/amount of ☐ percentage of complications post renal transplant by improving pre-transplant care in the frail and older adult renal transplant population.

By: greater than 50%.

To/By: decreasing hospital readmissions.

By: January 2022.

## Appendix D: Prisma Flow Chart



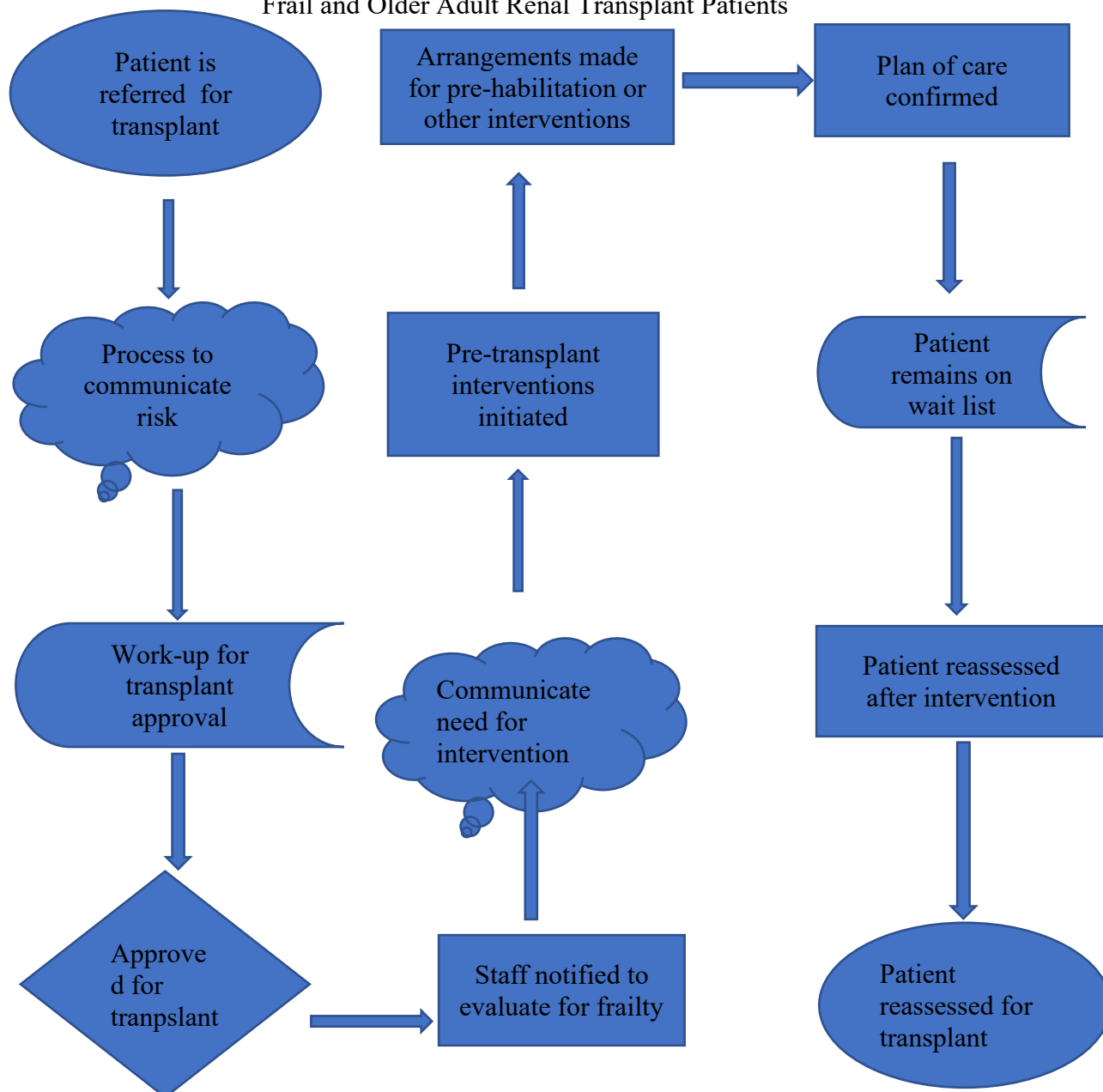
\*Consider, if feasible to do so, reporting the number of records identified from each database or register searched (rather than the total number across all databases/registers).

\*\*If automation tools were used, indicate how many records were excluded by a human and how many were excluded by automation tools.

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71. For more information, visit: <http://www.prisma-statement.org/>

## Appendix E: Pre-Implementation Flow Chart

Flow Chart: Effectiveness of a Frailty Assessment Index to Predict Early Readmission Rates in Frail and Older Adult Renal Transplant Patients

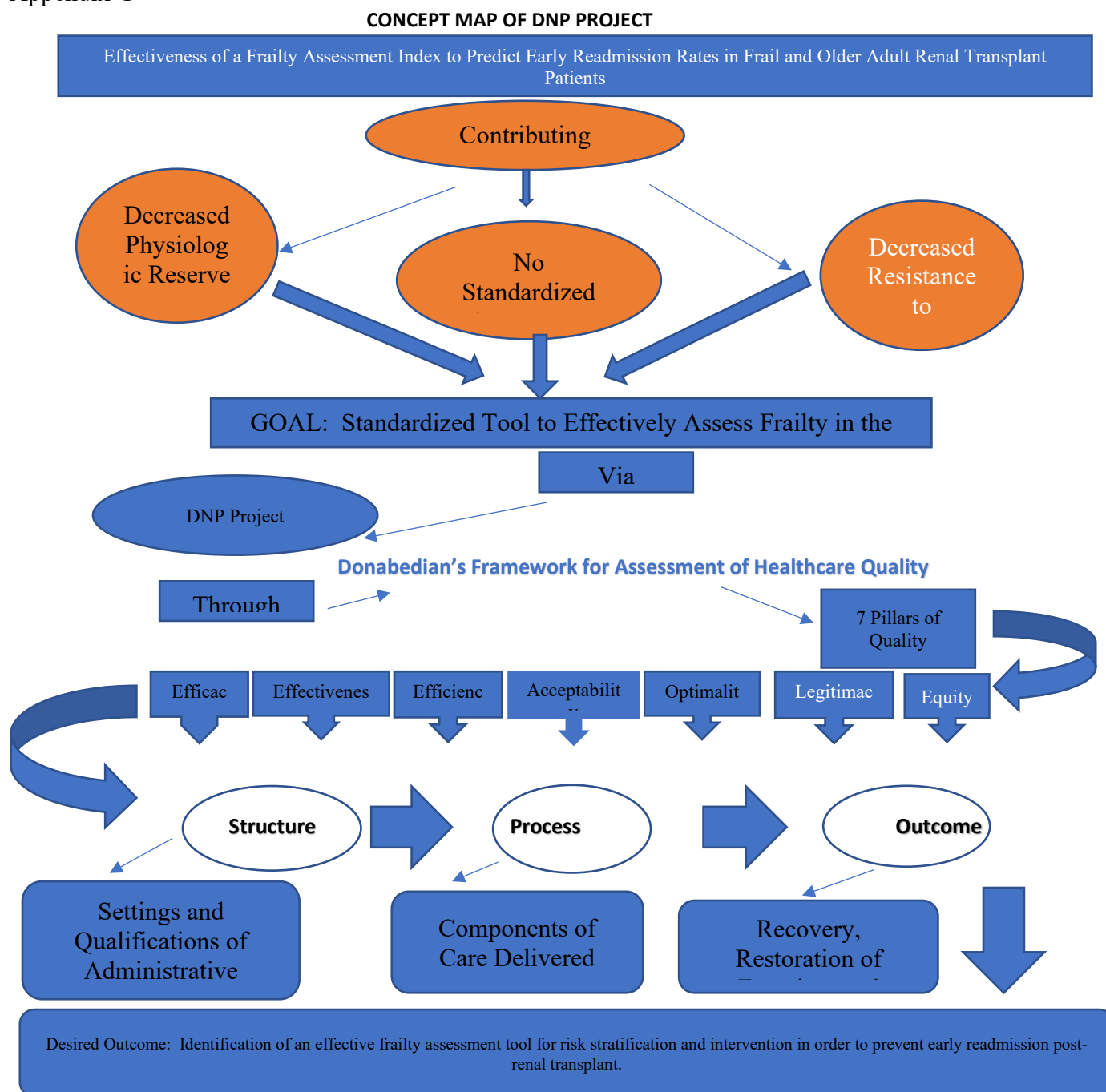


## Appendix F

**Data Collection Tool**

<b>Patient:</b>						
<b>Demographics</b>						
Deceased or Living Donor Transplant	Gender	Age	BMI	Dialysis Type or Preemptive	Years on Dialysis	Time from Referral for Transplant to Time of Listing
<b>5-Item Modified Frailty Index</b>						
Variable:					YES	NO
History of Diabetes Mellitus						
Congestive Heart Failure: New diagnosis or exacerbation Of chronic congestive heart failure within 30 days of surgery						
Hypertension Requiring Medication						
History of Chronic Obstructive Pulmonary Disease or Pneumonia						
Non-Independent Functional Status: Partially or completely dependent in activities of daily living within the last 30 days prior to surgery						
Score					Total Yes	Total No

## Appendix G



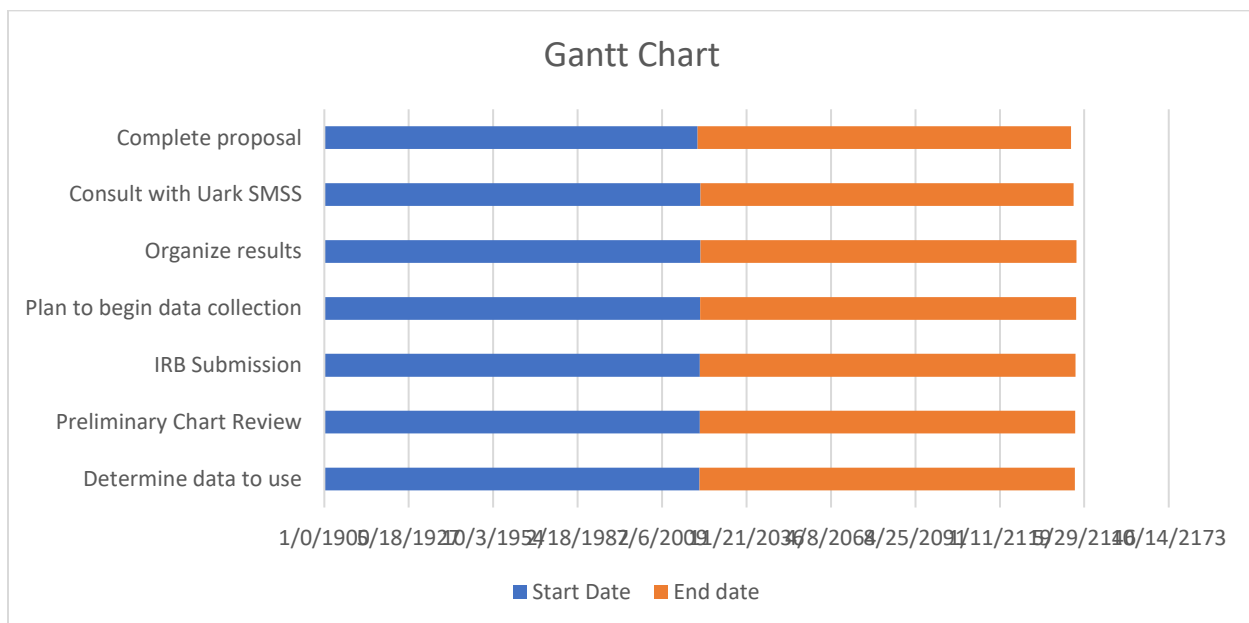
Appendix H: Evidence Table

Authors	Year	Country where research conducted	Theory guiding the study.	Independent (Treatment) and Dependent (Outcome) Variable(s)	Research Design	Sample Method and (N)	Data Collection Tools	Brief Summary of Results	Strength of evidence
De Pasquale, C., Pistorio, M., Veroux, M., Indelicato, L., Biffa, G., Bennardi, N., Zoncheddu, P., Martinelli, V., Giaquinta, A., Veroux, P.	2019	Italy	Kidney Transplantation involves profound psychological, relational, and social changes for patients and families. This study evaluates outcomes and potential causes of disparities related to personality profiles, awareness of disease, and family and social support among patients undergoing kidney transplant.	Patient characteristic and overall survival and graft survival rates of individuals undergoing living donor renal transplant and deceased donor renal transplant.	Systematic review	Literature search using the preferred reporting items for systematic reviews and meta-analysis (PRISMA), a checklist of 27 items based on the Cochrane Consumers and Communication Review model. Key words utilized included: self-efficacy, coping, health education, anxiety, depression, psychopathology, awareness diseases, social support, family support, quality of life, body image, adherence, compliance, psychosis, personality disorders, sleep disorders, neuropsychological disease, and kidney transplant. Databases included: MEDLINE, Scopus, Embase, PsycINFO, and Cochrane Library.	Physical Activities Scale for the Elderly; Resilience Scale; Instrumental Activities of Daily Living; Checklist of individual strength, functional impairments, Sickness, Impact Profile; Adherence Self-Efficacy Scale Kaufman Brief Disorders; Center for Epidemiologic Studies Depressive Scale	The authors categorized the outcome measures in outcome domains on the basis of consensus among study authors. They were sorted two domains according to the criteria of the Stanford Integrated Psychological Stability and Psychopathology which represent the most important aspects of recent literature on deceased donor kidney transplantation, psychosocial factors and patient's therapeutic adherence. Studies showed a high incidence of sleep disorders, with anxiety and depressive symptoms post transplant, unchanged 15 months post-transplant..	This study provided a systematic review of the literature over twelve years (2006-2018), focusing in particular on the patient's readiness level, illness management, and on possible psychopathology. Sixty-two studies were examined, and based on the Downs and Black checklist, most studies (n=32) were of high quality, 15 related to lifestyle, health education, and therapeutic adherence in post-renal transplantation, 17 studies concerned the existence of psychopathology

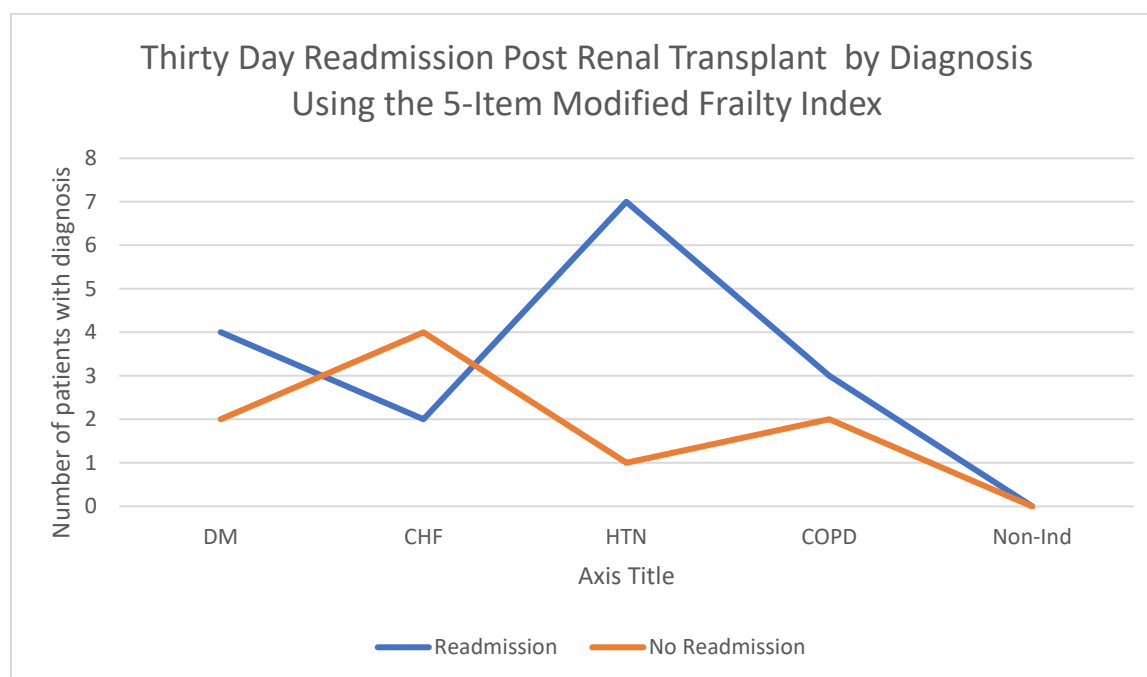
Authors	Year	Country where research conducted	Theory guiding the study.	Independent (Treatment) and Dependent (Outcome) Variable(s)	Research Design	Sample Method and (N)	Data Collection Tools	Brief Summary of Results	Strength of evidence
Panayi, A., Orkaby, A., Sakthivel, D., Endo, Y., Varon, D., Roh, D., Orgill, D., Nepol, R., Javedan, H., Bhasin, S., & Sinha, I.	2019	United States	The impact of frailty on surgical outcomes can be quantified as a prognostic indicator across all surgical specialties.	Evaluation of frailty and its relationship to surgical outcomes.	Systematic review and meta-analysis	Pubmed and Cochrane databased were screened.	Subgroup analysis for complication occurrence in the different modified frailty index score.	Frailty was associated with higher rate of all-cause complications and mortality.	Numerous studies were reviewed and well described.

Stuart, B., Timmons, Loh, F., Dai, M., Xu, J.	2020	United States	Older adult kidney transplant patients are at high risk for medication non-adherence post renal transplantation due to co-morbid conditions, decreased social support, cognitive disorders.	The objective of this study was to determine if a 2-item patient activation status (PAS) measure identifies individuals at risk of poor adherence.	PAS and medication adherence were assessed for respondents to the 2009 Medicare Current Beneficiary Survey and then compared using bivariate and multivariate tests.	A total of 940 Medicare beneficiaries with diabetes enrolled in Part D plans in 2009 were enrolled and the overall effect of PAS on medication adherence was assessed.	Medicare Current Beneficiary Survey	The overall effect of PAS on medication adherence was small; however, interactions of complacent/passive PAS with other characteristics associated with poor adherence. A single questions relating to taking medication lists to doctor visits may help identify patient subgroups prone to poor adherence in conventional practice.	Larger samples are necessary to validate and extend the findings.
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## Appendix I: Gantt Chart







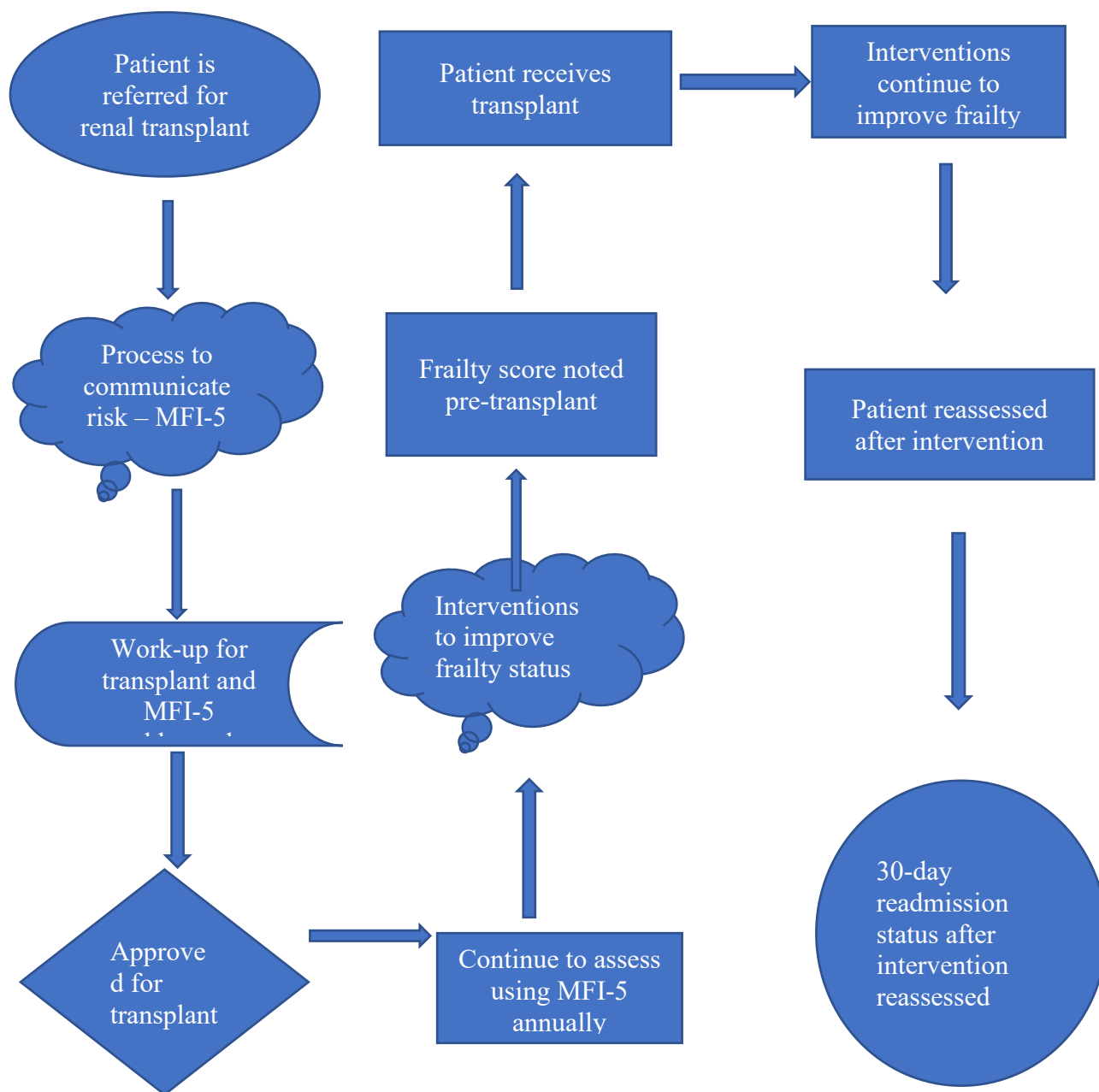
***Appendix J: Evaluation of the 5-Item Frailty Index to Predict 30-Day Readmission Post Renal Transplant***

The graph above describes the results of a preliminary review of post renal transplant charts using the 5-Item Frailty Index to determine its predictive value related to 30-day readmission post renal transplant. The most significant trend noted is the readmission of patient who are positive for hypertension on the scale. As more charts are reviewed and more trends identified, a plan for a more complete visual display can be made.

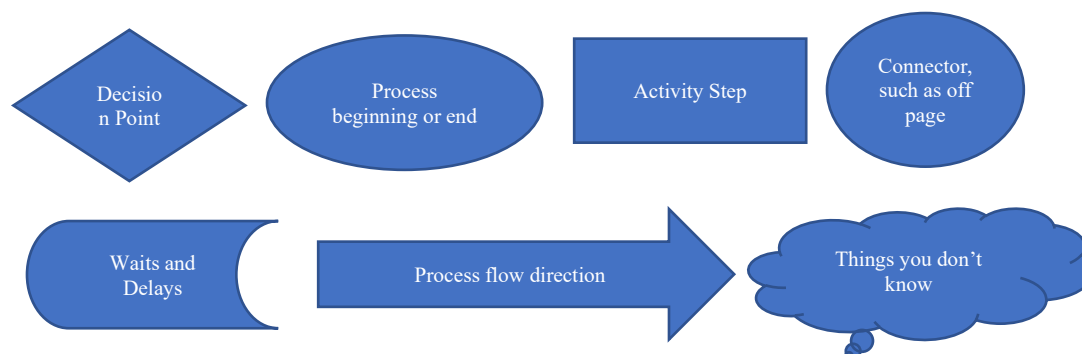
## Appendix K: Implementation Evolution Over Time

Implementation Timeline	Progress	New Changes
10-14-2022	UARK IRB Approval	
12-01-2022	Site IRB Approval	
12-20-2022	Team Meetings and Organization of Data	Provided transplant QI staff information related to the project.
12-22-2022	Preliminary Chart Reviews	<p>Performed preliminary chart review and found significant missing data.</p> <p>Determined that missing data was due to transition in charting between established computer system and newer alternative system.</p> <p>Received training related to newer system in order to identify location of information.</p>
1-30-2022	Repeat preliminary chart review.	100% of data located on repeat preliminary review.
2-1-2022 - ongoing	Implementation Evolution over time will continue during the implementation phase and will be documented here.	Complete retrospective chart review on all electronic medical records meeting inclusion criteria.

## Appendix L: Post-Implementation Process Flow Chart



### Process Flow Chart Key



**From:** Susan Kane Patton <[skpatton@uark.edu](mailto:skpatton@uark.edu)>  
**Sent:** Wednesday, June 16, 2021 8:36 AM  
**To:** Gould, Jon <[jgould@mcw.edu](mailto:jgould@mcw.edu)>  
**Subject:** 5 item frailty index

**ATTENTION: This email originated from a sender outside of MCW. Use caution when clicking on links or opening attachments.**

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Dr. Gould, I am looking for the owner of the mFI5 index. We would like to use this for a study on renal transplant patients. I was hoping you could point me in the right direction. Thank you.

Susan Patton, PhD, MHSA, APRN

**From:** Gould, Jon <[jgould@mcw.edu](mailto:jgould@mcw.edu)>  
**Sent:** Wednesday, June 16, 2021 9:47 AM  
**To:** Susan Kane Patton <[skpatton@uark.edu](mailto:skpatton@uark.edu)>  
**Subject:** Re: 5 item frailty index

Hi Susan. We came up with this concept for a study we published a few years ago. We don't own it, and many others have published using this metric as a reflection of frailty since then. I think you would be free to just go ahead and use this for your study.

JG

Jon C. Gould, MD, MBA  
 Alonzo P. Walker Chair of General Surgery  
 Chief, Division of Minimally Invasive and Gastrointestinal Surgery  
 Vice Chair for Quality, Department of Surgery  
 Professor of Surgery, Medical College of Wisconsin  
 Senior Medical Director for Clinical Affairs, Froedtert Hospital  
 8701 Watertown Plank Road  
 Milwaukee, WI 53226  
 414-955-1760



Institutional Review Board  
910 Madison Avenue, Suite 600  
Memphis, TN 38163  
Tel: (901) 448-4824

December 01, 2021

Marilyn Lawrence Barnett  
UTHSC - Nursing-Acute/Tert Care

**Re: 21-08451-XM**

**Study Title:** Effectiveness of a Frailty Assessment Index to Predict Early Readmission Rates in Frail and Older Adult Renal Transplant Patients

Dear Ms. Barnett:

The Administrative Section of the UTHSC Institutional Review Board (IRB) has received your written acceptance of and/or response dated December 01, 2021 and November 29, 2021 to the provisos outlined in our correspondence of November 30, 2021 and November 08, 2021 concerning the application for the above referenced project.

The IRB determined that your application is eligible for **exempt** review under 45 CFR 46.104(d) (4) (iii). Your application has been determined to comply with proper consideration for the rights and welfare of human subjects and the regulatory requirements for the protection of human subjects. In accord with 45 CFR 46.104(d) (4), informed consent is not required. Therefore, this letter constitutes full approval of your application (version 1.3) as submitted including:

- Data Collection Form.

**All of the above were stamped IRB-approved December 01, 2021. You must use the date-stamped versions of the study documents. Date-stamped materials are available in the *Informed Consent* and *Other Project Documents* folders in iMedRIS.**

**This study may not be initiated until you receive approval from the institution(s) where the research is being conducted.**

In addition, the request for waiver of HIPAA authorization in order to identify potential subjects and for the collection of data for the study is approved in accord with the criteria and review procedures specified at 45 CFR 164.512(i)(2). The waiver applies to the medical records of adult patients who underwent renal transplant at Methodist University Hospital between December 01, 2020 and December 31, 2021.

In the event that volunteers are to be recruited using solicitation materials, such as brochures, posters, web-based advertisements, etc., these materials must receive prior approval of the IRB.

Any alterations (**revisions**) in the protocol must be promptly submitted to and approved by the UTHSC Institutional

Review Board prior to implementation of these revisions. In addition, you are responsible for reporting any unanticipated problems, including reportable adverse events, involving risks to subjects or others in the manner required by the local IRB policy. Lastly, you must request to close your project when you have completed data analysis. All of the above should be submitted to the IRB via the appropriate form in iMedRIS.

**Please note that while the UTHSC IRB is still processing IRB submissions during the COVID-19 pandemic, you must follow UTHSC IRB's COVID-19 policy located on our website here: <https://uthsc.edu/research/compliance/irb/-covid-19.php> . You must review the policy and adhere to it as it relates to any and each of your UTHSC IRB-approved studies**

Sincerely,

A handwritten signature in cursive script that reads "Donna Stallings".

Signature applied by Donna L Stallings on 12/01/2021 06:39:59 AM CST

Donna Stallings, CIM  
IRB Administrator  
UTHSC IRB



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**To:** Marilyn Lawrence Barnett  
**From:** Justin R Chimka, Chair  
IRB Expedited Review  
**Date:** 10/14/2021  
**Action:** **Exemption Granted**  
**Action Date:** 10/14/2021  
**Protocol #:** 2110360608  
**Study Title:** Effectiveness of a Frailty Assessment Index to Predict Early Readmission Rates in Frail and Older Adult Renal Transplant Patients

The above-referenced protocol has been determined to be exempt.

If you wish to make any modifications in the approved protocol that may affect the level of risk to your participants, you must seek approval prior to implementing those changes. All modifications must provide sufficient detail to assess the impact of the change.

If you have any questions or need any assistance from the IRB, please contact the IRB Coordinator at 109 MLKG Building, 5-2208, or [irb@uark.edu](mailto:irb@uark.edu).

cc: Susan K Patton, Investigator

**MASTER CLINICAL PLACEMENT SITE AGREEMENT  
BETWEEN THE  
UNIVERSITY OF ARKANSAS  
COLLEGE OF EDUCATION AND HEALTH PROFESSIONS  
ELEANOR MANN SCHOOL OF NURSING  
AND  
Methodist Le Bonheur Healthcare**

This Agreement is made by and between Board of Trustees of the University of Arkansas, acting for and on behalf of the University of Arkansas, Fayetteville, College of Education and Health Professions – Eleanor Mann School of Nursing ("University"), with its principal address located at 606 N. Razorback Rd., Fayetteville, AR, 72701, ("University") and Methodist Le Bonheur Healthcare ("Placement Site"), with its principal address located at 1265 Union Avenue, 4th floor Shorb Tower, Memphis, TN 38104 .

**RECITALS**

- A. Placement Site is capable of providing an appropriate location for teaching and practical clinical experience for nursing students.
- B. Placement Site has an interest in assisting in the educational experience of University students.
- C. University is currently conducting educational programs granting the degree of Bachelor of Science in Nursing (B.S.N.), Master of Science in Nursing (M.S.N.), and Doctor of Nursing Practice (D.N.P) for which it desires a clinical site to further the training and experience of University's students.

**TERMS**

In consideration of the mutual promises and conditions contained in this Agreement, University and Placement Site agree as follows:

**1.0 Purpose and Definition**

1.1 Placement Site will provide a facility for University students to obtain appropriate clinical training and experience ("Clinical Experience"), and University will provide students to support the mission and efforts of Placement Site. The arrangement whereby one or more students shall participate in a Clinical Experience at the Placement Site shall be known as the "Clinical Program."

**2.0 Term, Renewal, and Termination of the Agreement**

2.1 This Agreement will be effective for a period of one year commencing on the date of the last authorizing signatures. Subject to the terms and conditions described below, this Agreement shall be extended automatically for successive one-year periods beginning August 1 of each succeeding year.

2.2 From time to time, the parties may discuss possible revisions of this Agreement which may be to their mutual interest.

2.3 This Agreement may be discontinued by either party, without cause, on six month's advance written notice.



### 3.0 Responsibilities of University

Responsibilities of University under this Agreement shall be as follows:

- 3.1 Be in charge of all instructional activities for participating students and work cooperatively with Placement Site to establish student schedules, assignment of students to supervisors at Placement Site, and patient assignments.
- 3.2 Assign to Placement Site only faculty who are properly credentialed and who agree to follow Placement Site rules and regulations.
- 3.3 Designate a faculty member who will serve as liaison with the Placement Site.
- 3.4 Use its best efforts to send a specified number of students to participate in the Clinical Program. General information about the Clinical Program will be communicated to students prior to each academic year.
- 3.5 Assign to Placement Site only those students who have met all University requirements and qualifications and who agree to follow Placement Site rules and regulations.
- 3.6 Notify students of their assignments with Placement Site and provide Placement Site, University faculty, and participating students with a copy of the written University rules and responsibilities that apply to the students in the Clinical Program.
- 3.7 Submit to Placement Site, two (2) weeks before any student's clinical placement is to begin, the names of the affiliating students, the dates of placement and the assigned areas; such list shall be revised into a final registration list within two (2) weeks after University's add/drop registration period ends.
- 3.8 Provide Placement Site with documentation that participating students have successfully completed any academic or training prerequisites and medical or immunization tests deemed necessary for participation in the Clinical Program.

### 4.0 Responsibilities of Placement Site

Responsibilities of Placement Site under this Agreement shall be as follows:

- 4.1 Provide opportunities for observation and practical experience conducive to student learning and allow faculty and students to select and arrange Placement Site learning experiences that meet clinical objectives.
- 4.2 Advise University of the number of students who can be accommodated at Placement Site.
- 4.3 Provide University faculty with written policies, procedures, standards or care and protocols of Placement Site, which shall govern students and faculty involved in the Clinical Program.
- 4.4 Familiarize faculty and students with policies and procedures for the Placement Site, including with respect to privacy of patient information.
- 4.5 Provide orientation so that all students can become acquainted with Placement Site facilities, policies, procedures, Placement Site faculty and staff, and the needs of individuals and/or groups with whom the students will be working.

5.0 Shared Responsibilities of University and Placement Site

5.1 University and Placement Site agree to work together to provide a quality Clinical Experience for students.

6.0 Requirements for Participating Students

In addition to any other requirements for participating students described in this Agreement, participating students shall be required to satisfy the following:

6.1 Students shall execute an agreement acknowledging their duties and responsibilities under Clinical Program, including their obligation to protect the privacy of patient information, a copy of which is attached and incorporated by reference;

6.2 Students shall carry and furnish evidence of health insurance;

6.3 Students shall be covered under a Student Blanket Professional Insurance policy obtained by the University with limits of \$1,000,000 per claim, \$3,000,000 aggregate; and

6.4 Students must obtain all immunizations recommended by the United States Public Health Service within six (6) months prior to beginning a Clinical Program and must present evidence of a negative chest x-ray or negative TB skin test.

7.0 Clinical Facilities

Placement Site agrees to provide the following:

7.1 Adequate facilities for Clinical Experience, including use of Placement Site's medical library, if one exists, or space for reference materials for students;

7.2 Opportunity for student practice and observation in patient areas and other areas of Placement Site;

7.3 Use of classrooms and/or conference room space for instructional purposes;

7.4 To the extent available, dressing rooms and locker space, or the equivalent, for students and faculty involved in the Clinical Program. Lockers for students may be shared; and

7.5 Use of dining room by students and faculty on the same basis as Placement Site employees.

8.0 Standards of Conduct; Discipline

8.1 University and Placement Site agree that all students and faculty assigned to Placement Site shall adhere to all rules, regulations, and standards applicable to University and Placement Site, including but not limited to standards of ethical and professional conduct as set forth in the student handbook or policies governing University's nursing program, and specifically including rules with respect to dress code and identification.

8.2 Any problems or questions that arise concerning an individual student shall be discussed with a University instructor, the Department Head for the School of Nursing, or the Dean of the College of Education and Health Professions or his/her designee.

8.3.3 Placement Site provides the student with notice of the problem and an opportunity for the student to respond before a final decision is made.

8.4 Placement Site reserves the right to exclude from its premises any student whose conduct or state of health is deemed detrimental to proper administration of Placement Site, provided Placement Site consults with and advises University's liaison prior to such exclusion or, if circumstances warrant, immediately thereafter.

#### 9.0 Authority for Placement Site Operations and Patient Care

Placement Site retains ultimate responsibility for all aspects of Placement Site operations, including but not limited to retaining ultimate responsibility for and supervision over patient care. University shall not be responsible for the performance of students at Placement Site.

#### 10.0 Student Records and Evaluation

10.1 Placement Site agrees to complete, on a timely basis, all evaluations and student records developed by University concerning student participation and performance in the Clinical Program.

10.2 The parties acknowledge that student educational records are protected by the Family Educational Rights and Privacy Act ("FERPA"), 20 U.S.C. § 1232, 34 CFR Part 99, and that generally student permission must be obtained before releasing student-specific data to anyone other than University. Facility shall use student educational records solely for the purposes of performing this Agreement, and such records shall not be redisclosed to any third parties.

10.3 Placement Site shall permit University to collect evaluation data from patients/clients who have received care from participating students, provided that information will be collected in an anonymous format and used solely for program evaluation.

#### 11.0 Investigation of Liability Claims

In the event there is actual or potential litigation against University, a participating student, or a University faculty member related to student or faculty actions taken in connection with Clinical Program, Placement Site agrees to provide University access and authority to investigate claims directly on-site and to obtain such information from Placement Site as it may require in the defense of any claims.

#### 12.0 Workers' Compensation

12.1 University and Placement Site agree that Placement Site is not responsible for any Workers' Compensation or disability claim filed by a student or by a University faculty member.

12.2 Students are not employees of University or Placement Site and are not covered by Workers' Compensation.

12.3 The faculty are employees of University and are covered accordingly under Workers' Compensation.

#### 13.0 Non-Discrimination

The parties agree to comply with all applicable federal, state, local, and university laws, ordinances and rules, and specifically agree not to unlawfully discriminate against any individual on the basis of race, color, religion, sex, age, disability, veteran's status, national origin or any other basis protected under Federal or state law.

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Site shall promptly notify University of any such reports and shall cooperate with any review of such matters conducted by the Institution.

15.0 Privacy of Health Information/HIPAA Compliance

15.1 It is the intent of the parties to comply with all applicable requirements of HIPAA in connection with this Agreement. During the time that the University's students and faculty are at the Placement Site and participating in clinical training involving Protected Health Information regulated by the federal HIPAA Privacy Regulations, these students and faculty will be considered a part of the workforce of the Placement Site with respect to HIPAA compliance and the students and faculty may use Protected Health information of the Placement Site for clinical teaching purposes.

15.2 Students are subject to the training requirements of the Placement Site and will attend the Placement Site's HIPAA awareness training. Additionally, the University shall advise all students of the importance of complying with all relevant state and federal confidentiality laws including HIPAA. The University agrees to provide students and faculty with training as to the requirements of the privacy provisions of HIPAA.

15.3 If students need to bring Protected Health Information back to the University for teaching purposes at the University, students shall use a limited data set to de-identify the identifying elements of information as required by HIPAA.

16.0 Relationship of the Parties

Placement Site is an independent contractor and shall not be deemed or construed to be an employee, agent, partner or joint venturer with University nor vice versa.

17.0 Severability

In the event any court of competent jurisdiction determines that any provision of this agreement is invalid or unenforceable for any reason, all remaining provisions will remain in full force and effect.

18.0 Governing Law

This Agreement shall be governed by and construed under the laws of the State of Arkansas. Any legal action or proceeding arising out of or relating to this Agreement shall be conducted exclusively within the State of Arkansas.

19.0 Successors and Assigns

This Agreement, and each and every provision hereof, shall be binding upon and shall inure to the benefit of the parties and their respective successors and assigns.

20.0 Notice

Any notice to either party hereunder must be in writing signed by the party giving notice, and shall be deemed given when mailed, postage prepaid, by U.S. Postal Service first class, certified, or express mail, or other overnight mail service, or hand delivered, when addressed as follows:

To University:  
Eleanor Mann School of Nursing  
806 N. Razorback Rd.

To Placement Site:  
Methodist Le Bonheur Healthcare  
1265 Union Avenue, 4th floor

This Agreement contains all the terms between the parties and may be amended only in w authorized representatives of both parties.

23.0 Independent Judgment

The parties represent and warrant to one another that this Agreement is entered into base party's independent analysis, with the advice of counsel, of the facts and legal principles re terms and conditions of this Agreement.

24.0 Time is of the Essence

The parties agree that time is of the essence in all respects concerning this Agreement.

IN WITNESS WHEREOF, this Agreement is hereby agreed to as the date last signed by authorize representatives of Placement Site and University:

UNIVERSITY:

Board of Trustees of the University of  
Arkansas, acting for and on behalf of  
the University of Arkansas, Fayetteville,  
College of Education and Health Professions -  
Eleanor Mann School of Nursing

by

SK Patton  
Susan Patton, PhD, MHSA, APRN  
Director

(Date)

5/20/21

by

Lewatis McNeal  
Lewatis D. MacNeal  
Assistant Dean - College of  
Education and Health Professions

05/26/2021

(Date)

Approved:

Charles F. Robinson  
Charles F. Robinson,

Provost and Executive Vice Chancellor  
for Academic and Student Affairs

5-27-21

(Date)

PLACEMENT SITE:

Methodist Le Bonheur Healthcare  
1265 Union Avenue, 4th floor Shc  
Tower, Memphis, TN 38104.

by

[Signature]  
(Signature)

Assistant CFO  
(Title)

5/18/2021

(Date)