**Study Protocol for ‘Patient Referral and Education Program prior to Renal Replacement Therapy (PREP-RRT)”: A Pilot and Feasibility Study**

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ABSTRACT

In the U.S., African Americans and other minorities are less likely to be seen by a nephrologist prior to dialysis. Pre-dialysis care is associated with a longer time to end stage renal disease (ESRD) and increased access to transplant and home dialysis modalities. The Patient Referral and Education Program prior to Renal Replacement Therapy (PREP-RRT) study is a pilot study to identify, educate and refer hospitalized African American patients with advanced CKD who may not be well linked to the medical system. The intervention is intended to motivate patients to increase CKD self-care and to improve communication and shared decision-making about RRT treatments among patients, their families and their providers. The primary outcome for the PREP-RRT study will be change in patient knowledge and attitudes about RRT options which will be assessed by the previously validated Kidney Knowledge Survey (KiKS). Secondary outcomes of interest are patient satisfaction with education, time-to-event for nephrology appointment, appearance at transplant center, likelihood of fistula, self-care dialysis at dialysis initiation, or documentation of patient decision not to initiate RRT.

***Keywords:*** Chronic kidney isease, health disparity

1. Background

End stage renal disease (ESRD) affects over 600,000 patients in the United States and represents $49 billion in health care costs and 7.2% of Medicare spending (Saran et al., 2018). In addition, patients on dialysis experience high morbidity and mortality with a hospitalization rate of 1.84 per patient year and a 5-year survival rate of 35% (Saran et al., 2018).Several therapies have been shown to reduce costs, morbidity, mortality and to improve quality of life in patients with ESRD; however, these therapies remain underutilized (Berger, Edelsberg, Inglese, Bhattacharyya, & Oster, 2009; Cameron, Whiteside, Katz, & Devins, 2000; Lacson Jr, Lazarus, Himmelfarb, Ikizler, & Hakim, 2007; Laupacis et al., 1996; Saran et al., 2018). For example, using arteriovenous (AV) fistulas for hemodialysis (HD) access instead of catheters is associated with 50% reduction in mortality, yet only 16% of HD patients begin dialysis with a fistula (Polkinghorne, McDonald, Atkins, & Kerr, 2004; Saran et al., 2018). While evidence suggests that peritoneal dialysis (PD) is associated with reduced costs and improved outcomes during the first five years, only 7% of all incident dialysis patients used PD despite estimates that up to 75% of dialysis patients have no medical or social contraindications to PD (Berger et al., 2009; Mehrotra, Marsh, Vonesh, Peters, & Nissenson, 2005; Mendelssohn et al., 2008; Saran et al., 2018). One study found that 70% of incident dialysis patients had not been presented with PD as an option (Goovaerts, Jadoul, & Goffin, 2005). Compared to dialysis, renal transplant costs less and reduces mortality by 50% (Saran et al., 2018). However, only 30% of the prevalent ESRD population has been transplanted and an additional 17% are on the renal transplant waitlist (Saran et al., 2018).

Commonly described as a “silent disease”, many people don’t experience symptoms of CKD until advanced stages or initiation of dialysis is required. Patients experience non-specific symptoms or no symptoms which can reduce a person’s motivation to manage physical and mental health, behavioral changes, and treatment planning. Essential to prevention are effective nephrologist-patient partnerships which increase patient knowledge, self-management, and understanding for informed decision making and treatment planning. Successful treatment outcomes of managing CKD include diet, fluid, and exercise management, adherence to blood pressure and glucose medications (Curtin et al., 2008; Novak, Costantini, Schneider, & Beanlands, 2013).

Pre-renal replacement therapy (RRT) patient education delays time to ESRD and leads to reduced central venous catheter use, improved uptake to self-care dialysis and increased access to transplant for patients with ESRD (Cass, Cunningham, Snelling, & Ayanian, 2003; Lacson Jr et al., 2011; Prakash et al., 2010). Yet, many patients with advanced CKD do not receive guideline recommended care and education. Most pre-RRT education occurs while patients are under a nephrologist’s care (Manns et al., 2005; Wu et al., 2009). Prior work has demonstrated barriers at each step in the process of referral to nephrology (Boulware, Troll, Jaar, Myers, & Powe, 2006; Goovaerts et al., 2005; Marrón et al., 2010). Additionally, some patients who present to nephrology still are not appropriately presented with all RRT options (Marrón et al., 2010). Prior work has shown that independent of what modality patients choose, patient education prior to renal replacement therapy can improve patient outcomes and patient satisfaction with their modality (Sheu et al., 2012).

African American patients are particularly at risk for lack of identification, referral or education. African Americans and other minorities are less likely to be seen by a nephrologist prior to dialysis initiation (Prakash et al., 2010). This lack of pre-dialysis care and education is associated with African Americans’ lower likelihood of pre-emptive transplant, choosing PD or having an AV fistula in place for HD (Prakash et al., 2010). In addition, ethnic and racial minorities are more likely to be uninsured/underinsured which leads to difficulties in accessing care, particularly sub-specialty care (Saran et al., 2018; Stanley, Cantor, & Guarnaccia, 2008). African Americans also experience less shared decision-making across all domains—information sharing, provider recommendations and decision-making (Sheu et al., 2012). Patients cite limited time for decision-making due to urgent initiation of dialysis as well as limited awareness and understanding of other RRT modalities (Sheu et al., 2012; Song & Ward, 2014).

The hospital is an important, often overlooked, site for patient education and linkage to nephrology care for patients with advanced CKD. Many patients with advanced CKD are hospitalized in the three months prior to dialysis initiation, which represents an opportunity to identify existing CKD and to use a multidisciplinary approach to preventative care, patient education, and patient-provider planning for future RRT needs (Mix et al., 2003). Patients are often a ‘captive audience’ while hospitalized and may be more receptive to education efforts due to their concerns about their acute illness (Anderson, Deepak, Amoateng‐Adjepong, & Zarich, 2005; Wexler et al., 2012). Finally, many patients who have difficulty accessing outpatient care—due to limited transportation, limited mobility, disinterest or lack of insurance—often appear in an inpatient setting. One way to address African Americans reduced access to pre-RRT care is to recruit and education patients in the hospital.

During hospitalizations, African American patients may benefit from CKD awareness, CKD education, and pre-RRT planning and linkage to providers. The Patient Referral and Education Program prior to Renal Replacement Therapy (PREP-RRT) study is intended to capture the perspective of and be tailored to African American hospitalized patients who may not be well linked to the medical system. PREP-RRT seeks to inform and educate African American patients with advanced CKD, along with their direct medical teams, can advocate for appropriate care, demonstrate self-sufficiency, increase RRT planning outcomes and link to appropriate outpatient care. This paper will outline the intervention protocol for the PREP-RRT study.

*Primary Hypothesis*

Knowledge gaps related to CKD and RRT can be feasibly addressed by a tailored intervention among hospitalized African American patients with advanced CKD.

*Secondary Hypotheses*

Using motivational interviewing techniques, reducing knowledge gaps about CKD and RRT, and making referrals to outpatient care will increase patient intent to access and actual access to pre-RRT care.

**2. Methods**

**2.1 Study design**

PREP-RRT is an inpatient hospital-based intervention pilot study. After screening and verbal consent are acquired by the research assistant (RA), the intervention will occur in three phases which will take place in the patient’s private room. In the first phase, the RA will facilitate a pre-education CKD survey. For patients with low literacy or poor vision, the RA can read the questions to the participant and record their answer. The RA will leave education materials with the patient. The RA will then contact the patient educator (social worker). In the second phase, the patient educator will lead a semi-structured, in-person education session using culturally-tailored education materials that focus on CKD self-care, RRT planning, and patient concerns. In addition to providing education, the patient educator will incorporate motivational interviewing to stimulate the patient’s commitment to action to improve their CKD self-management, interaction with the medical system and commitment to RRT selection. The patient educator will contact the RA after completing the education session. In the final phase, the RA will provide the participant with the post-intervention survey. After completion of all three phases, participants will receive a $25 gift card. Participants will be contacted at 30 days post-discharge to complete a survey post-intervention. Participant CKD health utilization will be compared to that of historic controls.

**2.2 Recruitment and patient participation**

The PREP-RRT study will be conducted at an urban Midwest medical center general medicine inpatient service. Participants will be hospitalized African American patients who are English speaking, between the ages of 18 and 75 years old with an estimated glomerular filtration rate (GFR) ≤ 45 (or CKD stage 3B-5, not yet on dialysis or received kidney transplant) and without significant cognitive impairment. Inclusion and exclusion criteria for historic control and intervention groups are identified in Appendix 1.

This study will be a substudy of the Hospitalist Project, an ongoing clinical study that examines a variety of outcomes of patients hospitalized on our general internal medicine services and includes administrative data, inpatient interviews and 30 day follow-up by phone (Meltzer et al., 2002). The Hospitalist Project staff will obtain basic demographic information and medical history. Per Hospitalist Project protocol, staff also obtains permission to contact patients post-discharge and to access their medical records (i.e., at UCMC, other medical systems and Medicare linkage). All inpatients recruited to the Hospitalist Project will be screened daily by the RA to identify patient eligibility for the PREP RRT study. We obtained all appropriate ethical and institutional review board approval for this protocol.

**2.3 Interventions**

The intervention strategies that will be used in this study are motivational interviewing (MI) and psychoeducational techniques to increase patient understanding of their illness, decision making, and coping skills. The patient educator will engage in semi-structured face to face interview with subjects during hospitalization to discuss the contents in the education materials. The educational materials in the intervention includes a 19-page booklet that discuss the function of kidneys in the body; the definition and cause of chronic kidney disease; measuring kidney function; how to manage diet, fluid, and kidney treatment; renal replacement therapy options including hemodialysis, peritoneal dialysis, transplant, dialysis access, and conservative management; socio-economic barriers to access and care; and supportive resources. The booklet contains graphics, racially concordant pictures and information geared to low-literacy populations. Moreover, increased education empowers patients to make informed healthcare decisions and shared decision making with healthcare provider

The patient educator will also use motivational interviewing techniques to increase participants’ self-motivation to act (Rollnick & Miller, 1995). Using MI, the patient educator will help participants to identify their health care goals and recognize the discrepancy between their short and long-term goals and behavior. The patient educator will assess internal and external barriers to treatment, use MI to explore participant the ambivalence, and offer supportive referrals reduce psychosocial stressors and barriers (i.e., managing multiple comorbidities, unaddressed mental health issues, finances, and access to healthy lifestyle options). Upon completion of the intervention, the patient educator will share “Next Steps” section of the educational materials and share with case manager, inpatient social worker, and medical team for appropriate follow-up and linkage to outpatient care. Potential next steps may include meeting with a dietician, inpatient diabetes educator, insurance and prescriptions concerns, transportation to medical appointments, and outpatient scheduling in Nephrology and Transplant clinics post discharge.

**2.4 Measures and outcomes**

The surveys given before and after the intervention will allow for pre- post assessment of change in knowledge (immediate post-intervention, 30 days and 60 days post-intervention).

*Primary Outcome: Patient Knowledge*

The **primary outcome** will be change in patient knowledge, attitudes and behavior about CKD and ESRD treatment options*.* To assess knowledge of kidney disease, we will use the previously validated Kidney Knowledge Survey (KiKS) (Wright, Wallston, Elasy, Ikizler, & Cavanaugh, 2011).In addition, we will use an investigator-developed instrument to assess knowledge and preferences about ESRD treatment options. The evaluation of the PREP-RRT study will be measured using pre- and post-test questionnaires administered by the research assistant to examine patient health care experience, understanding of health and kidney disease, and kidney failure treatment knowledge and preferences. Data from the post-intervention questionnaire will be used to analyze the effectiveness on increasing intent to initiate change to diet, physical activity, medication compliance, management of co-morbidities, causes and risks for CKD, and RRT preferences and planning outcomes.

*Secondary Outcomes*

**Secondary outcomes** will include patient satisfaction with education, time-to-event for nephrology appointment, appearance at transplant center, likelihood of fistula, self-care dialysis at dialysis initiation, or documentation of patient decision not to initiate RRT. MI techniques are heavily utilized during the intervention. Motivation for change will be measured using a 5-point self-report questionnaire across likelihood, importance, and intent. Patients will be asked how likely they are to make changes to diet, exercise regimen, and kidney care over the next 3 months. The 5-point Likert scale will range from extremely unlikely, most unlikely, not sure, most likely, extremely likely, and NA/refused to answer. We will use investigator developed instruments to measure patient likelihood, importance, and intent.

For longer term outcomes (i.e., time-to-event for nephrology appointment, appearance at transplant center, likelihood of fistula, self-care dialysis at dialysis initiation), we will compare participant outcomes to those of historic controls, similar patients selected from the Hospitalist Project using the same screening method as participants starting 6 months prior to implementation.

**2.5 Statistical Methods**

*Power Calculation*

Although several outcomes will be measured, the sample size is calculated based on the primary outcome, difference in patient knowledge pre- and post-intervention. Because this is a pilot study to determine preliminary efficacy estimates, minimum power calculations were based on best estimates from the validated knowledge tool used for the primary outcome. In their work validating a 28-item knowledge tool, Wright et al. found a baseline average knowledge score of 66% (18.5/28) +15% (4.2/28) (Wright et al., 2011).  A significant improvement in knowledge would be to increase the knowledge score to >82% (>23/28), which would be greater than one standard deviation above the baseline validated score. Therefore, to demonstrate a clinically significant increase of 6% or 4.5 points, the study will enroll 62 participants to achieve 80% power.

*Data Analysis*

Descriptive statistics will be used to summarize the characteristics for patients including patient demographics, health literacy, self-efficacy, and quality of life at baseline. The primary analysis will be to evaluate the effects of hospital-based RRT education intervention in CKD patients. For the primary outcome, patient knowledge, attitudes and behavior (intent) we will use paired t-test to analyze the changes between pre- and post-intervention. For longer term outcomes such as time-to-event for nephrology appointment, appearance at transplant center, likelihood of fistula, self-care dialysis at dialysis initiation, we will use historic controls, the outcomes of similar patients at UCMC in the Hospitalist Project beginning 6 months prior to implementation. Our ability to create the UCMC cohort of controls and to follow their outcomes is feasible due to the data collection apparatus of the Hospitalist Project where we have lab and survey data, a planned post-discharge call as well as patient consent to access all of their medical records. Cox proportional hazards models will be employed to compare the differences between patients with intervention and historic controls in time to the outcomes of interest. Logistic regression will be used to compare the differences between patients in the intervention and historic controls for the binary outcomes.

**3. Discussion**

African American experience disparities in ESRD outcomes due to more rapid progression to ESRD and reduced access to effective ESRD treatments (Choi et al., 2007; Hao et al., 2015; Hsu, Lin, Vittinghoff, & Shlipak, 2003; Saran et al., 2018). Pre-dialysis patient education is an under-utilized option to improve knowledge and outcomes for patients with chronic kidney disease and to improve access to effective renal replacement therapy modalities. The hospital as the site of intervention is innovative and may help to reduce disparities because many patients who have difficulty accessing outpatient care, due to limited transportation, limited mobility or lack of insurance, often appear in an inpatient setting. Hospitalizations represent “missed opportunities” to provide RRT education and planning to help CKD patients make informed choices about their care that aligns with their preferences.

This study’s design involves several innovations and contains multiple strengths. First, the study focuses on African American patients and uses culturally tailored, literacy sensitive education materials and a racially-concordant research team. In addition, the study attempts to over barriers to care by recruiting and educating patients while they are hospitalized. Motivational interviewing supports patients in resolving ambivalence and developing autonomy in the decisions regarding lifestyle changes and medical care. In conjunction with MI, it is beneficial for patients to learn about kidney disease and treatment options. Education encourages patients to make informed decisions and assume a collaborative role in their treatment with medical providers to reduce potential harm and align with patient choices. The patient educator also is a trained social worker who is also able to improve access to appropriate outpatient resources.

Limitations of the PREP-RRT study include lack of randomization and sample size and data comparison of control group at baseline which reduces generalizability of results along with significant statistical relationships in the data. Furthermore, the patient educator may have exhibited bias as each interview was tailored to a patient’s emotional response, needs, and concerns related to CKD stage and RRT. Lastly, survey questions are closed-ended which enables patients to select options but does not give insight into why they made those selections.

**4. Conclusion**

African Americans have reduced access to transplantation and home dialysis and more rapid progression to ESRD compared to their White counterparts. Prior work has found that many African American patients with advanced CKD and lacked knowledge of transplantation and home dialysis modalities. The PREP RRT intervention will identify, educate and motivate patients to increase CKD self-care and to improve communication and shared decision-making about RRT treatments among African American CKD patients, their families and their providers.

**Declarations**

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**Appendix 1**

Inclusion and Exclusion Criteria for the Patient Referral and Education Program prior to Renal Replacement Therapy (PREP-RRT) study

1. Inclusion criteria:
	1. African American
	2. Adult patients (18-75)
	3. GFR ≤ 45 (or CKD stage 3B-5)
	4. English speaking
2. Exclusion criteria:
	1. Significant cognitive impairment
	2. Patients with proxy
	3. Currently on renal replacement therapy (dialysis or transplant)
	4. Currently in the ICU
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