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Evaluating the Impact of a Standardized Education Class on a Person Diagnosed with
Chronic Kidney Disease, Stage IV

Presented to the Faculty of the School of Nursing
The George Washington University
In partial fulfillment of the
requirements for the degree of
Doctor of Nursing Practice

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Abstract

Background: Chronic kidney disease (CKD) is a complex, progressive, and costly disease impacting more than 26 million Americans. Providing effective education is necessary so the patient may actively participate in managing the disease process, but the effectiveness of the delivery of education to the patient with CKD is not well-known.

Objective: To evaluate the effectiveness of a standardized education class on the basic kidney knowledge of persons diagnosed with CKD, stage IV.

Method: This pilot study, using a one-group pre and post-test design, was conducted in an outpatient nephrology clinic located in Washington, D.C. The study participants, recruited using census sampling, completed a kidney disease-specific knowledge questionnaire prior to a standardized education class, and then completed the same questionnaire immediately after the class. A Wilcoxon Signed-Ranks test and descriptive statistics were utilized to examine the mean kidney knowledge and summarize the findings.

Results: A total of 14 patients participated in this study. Participants' mean age was 63 years, most were female (64%) and Black/African American (79%). Thirty-six percent were not married, 43% reported having a high school diploma or equivalent, and 43% rated their overall health status as good. The study results concluded that the post questionnaire scores were significantly higher than the pre questionnaire scores ($Z = -3.299, p = 0.001$).

Conclusions: This pilot study showed that providing a standardized education class is associated with higher basic kidney knowledge. While compelling, further studies are needed to determine knowledge retention, and support these findings with a larger sample size.

Evaluating the Impact of a Standardized Education Class on a Person Diagnosed with Chronic Kidney Disease, Stage IV

Background and Problem Statement

Chronic kidney disease (CKD) is a complex, chronic illness characterized by a progressive worsening of kidney function occurring over an unpredictable period of time (National Kidney Foundation [NKF], 2002). The NKF identified five stages of CKD based on the glomerular filtration rate (GFR), which indicates – in milliliters per minute – how effectively the blood filters through the kidney (NKF, 2002). A decreased GFR indicates a worsening stage of CKD. Stage I represents the least severe form of CKD and is defined as a normal GFR (greater than 90mL/min) with signs of mild functional or structural kidney damage (NKF, 2002). Stage II, mild kidney damage, is evident when the GFR has declined to 60-89mL/min (NKF, 2002). For a patient to be diagnosed with Stage III, signs of moderate kidney damage are present and the GFR falls to 30-59mL/min (NKF, 2002). Often patients in Stages I through III have few symptoms (NKF, 2002). Chronic kidney disease Stage IV (CKD-IV) indicates severe kidney damage and a significant decline in the GFR (15-29mL/min). Frequently, patients in Stage IV will present with concomitant, uncontrolled hypertension (HTN) (NKF, 2002). The most severe form of CKD – Stage V or end stage renal disease (ESRD) – occurs when the GFR is less than 15mL/min (Damien, Lanham, Parthasarathy & Shah, 2016; National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK], 2016; NKF, 2002). When a patient is diagnosed with ESRD, the kidney function has declined significantly enough that life is not sustainable without an intervention, such as dialysis or kidney transplant (Damien et al., 2016). Determining the timing and nature of patients' trajectories through each CKD stage contributes to the complexity of this disease (Damien et al., 2016; Green & Boulware, 2016).

Approximately 20 million Americans suffer from CKD (Stages I through IV) and more than 661,000 have ESRD (NIDDK, 2016). While the number of patients diagnosed with the disease is small, and it affects less than 1% of the population in the United States (U.S.), the incidence of CKD has increased by more than 67% in the past two decades (Young, Chan, Yevzlin & Becker, 2011; Zuber & Davis, 2013). Moreover, the costs associated with any stage of CKD are 85% higher than those without the disease (Damien et al., 2016).

Chronic kidney disease, Stage IV is the leading cause of ESRD and the incidence of CKD-IV is expected to increase given the aging population (NIDDK, 2016). As a result, CKD and ESRD are considered major health problems and affect a disproportionate share of Medicare beneficiaries (Healthy People 2020, 2017; Young et al., 2011). Nearly 50% of patients diagnosed with CKD-IV are covered by Medicare and approximately 25% of the overall Medicare budget is spent on patients with CKD-IV and ESRD (Healthy People 2020, 2017; Young et al., 2011). Among the 65% of patients with CKD who require dialysis, Medicare spending was \$87,945 per patient in 2011 (Damien et al., 2016).

Improvements in blood pressure control, blood glucose control, and medication adherence can delay the progression of CKD (Tuot et al., 2015). For that reason, kidney disease education aimed at improving patient's knowledge of the disease process is essential when treating patients with CKD and ESRD. Because patients with CKD face treatment regimens that are complex and made more complicated by treatment for comorbidities, patients must be experts in their self-care, medication management, and prevention of further injuries to the kidney (Finkelstein et al., 2008). Additionally, because patient education may delay patient's initiation of dialysis, it is an important adjunct for delaying the disease progression (Finkelstein et al., 2008). In a study conducted by Davison (2010), over 90% of patients diagnosed with

CKD-IV reported they had neither been informed of their prognosis nor the various renal replacement modalities; yet, consensus exists regarding the importance of sharing this information with patients. For example, Healthy People 2020 aims to decrease the new cases of CKD by increasing patients' awareness of their impaired renal function, among other interventions (Healthy People 2020, 2017). The National Kidney Foundation–Kidney Disease Outcomes Quality Initiative (NKF-KDOQI) clinical practice guidelines recommend that patients receive education tailored to their CKD stage (Inker et al., 2014).

In recognition for the need for effective patient education, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) authorized education benefits for Medicare-eligible recipients effective January 1, 2010 (NKF, 2015; Zuber & Davis, 2013). The MIPPA benefit targets patients with CKD-IV because this population is at greatest risk for developing ESRD (NKF, 2015). This education benefit is aimed at slowing the progression of CKD, counseling patients regarding the various renal replacement options, and promoting informed decision making (Zuber & Davis, 2013). Yet, despite Medicare recipients being offered this benefit, it is known to be underutilized with less than 7% of patients Medicare-eligible recipients with CKD-IV receiving CKD education in 2010-2011 (NKF, 2015; Zuber & Davis, 2013). In a study by Finkelstein et al. (2008), the researchers found that a cohort of patients, diagnosed with CKD Stage III-V, reported limited knowledge of their disease and renal replacement options.

Hypothesis and Specific Aim

It is hypothesized that a standardized education class could be effective in improving kidney disease-specific knowledge in patients with CKD-IV. Thus, the specific aim of this study was to determine the effectiveness of a standardized education class using the Kidney Knowledge Survey (KiKS) questionnaire before and after a 60-minute structured education class

in an out-patient nephrology clinic located in Washington, D.C. (see Appendix A for the KiKS survey).

Research Question

What effect does a formal, 60-minute, structured education class have on these patients' knowledge of kidney disease?

Significance

Incorporating patient education is fundamental in terms of improving patient outcomes and slowing the progression of CKD (Inker et al., 2014). Still, evidence regarding the effectiveness of CKD education and the contribution to impacting outcomes is limited (Green & Boulware, 2016). As the incidence of CKD in the U.S. continues to rise, effectiveness of the education needs to be further evaluated; therefore, this proposed study will contribute to further evaluating the effectiveness of the education along with supporting a patient-centered approach, one of the six aims as defined by the Institute of Medicine's Triple Aim (Institute for Healthcare Improvement [IHI], 2017). Hence, effective CKD-IV education serves to bridge the communication gap between the patient and the provider (Green & Boulware, 2016).

Literature Review

To better understand the nature and type of patient education that has been shown to be most effective in CKD, a review of literature was conducted. CINAHL and Scopus were used as primary bibliographic databases and combinations of the following search terms were used: *chronic kidney disease, chronic renal failure, education, randomized controlled trials, and benefits*. Only studies published in English and available in full text format were included. Initially, a total of 112 titles were identified. Based on review at the title and abstract levels, studies were excluded if they did not examine and educational intervention for adult patients

diagnosed with CKD or ESRD. Ultimately, seven titles were retained for inclusion in this review.

Mason, Khunti, Stone, Farooqi and Carr (2008) performed a systematic review of randomized controlled trials (RCTs) of educational interventions for patients with early CKD (pre-dialysis) and those receiving dialysis. The review included 22 studies from 5 different countries (U.S., Canada, United Kingdom, The Netherlands, and Taiwan). The inclusion criteria included 1) patients 18 years of age or older, 2) included structured classes with informational and psychological components, 3) a control group that received usual or routine care, and 4) evaluated clinical, knowledge, behavioral, and/or psychological outcomes. Only 5 of the studies included patients in CKD-IV while the remaining studies focused on patients receiving dialysis. Because of each study's limitations (i.e. sample size, lack of a valid tool, and short follow-up) and their collective heterogeneity, the authors contended that more information was needed to evaluate the effectiveness of education; however, there was some indication that a lack of patient education contributed to patients' disease severity and emergent start to dialysis (Mason et al., 2008).

Mehrotra et al. (2005) conducted a pilot study of 229 patients who started dialysis in one specific region in Southern California over a one-month period. A survey was administered to collect information regarding the patient's knowledge about their disease process and the various renal replacement options. The survey demonstrated that 30% of the respondents were not aware of the various renal replacement options prior to starting dialysis and 74% of the respondents had not been provided with information regarding kidney transplant. Moreover, only 28% of the patients knew they were approaching kidney failure despite the fact that 29% of the patients had seen a nephrologist for longer than one-year. The findings from Mehrotra et al. (2005) suggest

limitations in pre-dialysis education. According to Moist and Al-Jaishi (2016), patients who understand their treatment options are more prepared to make decisions based on their individual lifestyle reducing decisional conflicts amongst patients and providers. Opportunities to evaluate educational interventions exist to ensure patients are active participants in their disease process promoting a patient-centered approach (Moist & Al-Jaishi, 2016).

Binik et al. (1993) performed a randomized study, identifying 204 patients diagnosed with various stages of CKD, who were described as having deteriorating renal function and considered pre-dialysis but did not identify patients' kidney disease stage. The study randomized patients into groups – one that received routine education from the kidney provider and the other group that received an “enhanced educational program” designed specifically for this study (Binik et al., 1993, p. 373). The enhanced educational program consisted of a slide-lecture delivered in an individualized setting that provided the patient with information covering the basic function of the kidney, dietary recommendations, and renal replacement modalities. The enhanced educational program lasted approximately 75-minutes and was conducted by a trained research assistant. Additionally, each patient left with a 22-page booklet that contained the contents of the educational program. The Kidney Disease Questionnaire (KDQ) – a 13-item, multiple choice test designed to measure the patient's understanding of ESRD treatment – was administered before and after both forms of education. Patients in the enhanced educational program demonstrated an improved understanding when compared to patients in the other situations. Also, Binik et al. (1993) reported that patients who received the enhanced educational program survived an average of 4.6 months longer than the non-enhanced intervention. While the KDQ is a validated tool, it is not an adequate tool to assess the patient's knowledge and behavior.

Chen et al. (2015) performed a retrospective analysis of the effects of a multidisciplinary care program that included an educational component on pre-dialysis patients in a single-center in Taiwan. The study compared two groups of patients, one group participated in the multidisciplinary program ($n=592$) and the other did not ($n=614$). The multidisciplinary care program included a detailed interview which assessed the patient's baseline kidney knowledge, provided the patient with close follow-up visits with the renal team, educational programs provided by trained staff, and frequent laboratory testing (Chen et al., 2015). Additionally, once a patient reached a particular threshold, indicating the likelihood of requiring dialysis, a more intensive approach was provided to prepare the patient for the initiation of dialysis (Chen et al., 2015). The study evaluated mortality, the approach used to initiate dialysis, overall medical costs, as well as some important clinical indicators. Overall, results demonstrated a 30.6% reduced risk of dialysis among patients in the multidisciplinary care program versus patients in the control group (Chen et al., 2015). There was also a significantly lower annual cost per patient for those in the multidisciplinary care program, and when specifically comparing the two groups' frequency of emergency department visits, the non-multidisciplinary care group sought emergency department services more often (Chen et al., 2015). Of importance, their study demonstrated the most prominent impact, of all the variables, were on those patients in CKD-IV (Chen et al., 2015). While the findings reported by Chen et al. (2015) support the importance of kidney education, the outcomes reported focused on clinical and financial outcomes.

Walker, Marshall and Polaschek (2013) conducted a pilot study in two nurse practitioner (NP)-led primary care offices in New Zealand to evaluate the impact of education on clinical outcomes and self-management knowledge and skills of 52 patients with CKD. The intervention was an individualized care plan provided every 2 weeks for a total of 12 weeks. During the

appointments, medication adherence was assessed, medication adjustments were made, clinical targets were evaluated, and on-going education was provided. Patients were also provided with a self-management booklet to chart on-going clinical indicators for their reference. At the end of 12 weeks, improvements were found in most clinical variables, but there were some limitations found in the self-management domain as patients continued to report poor knowledge of their disease process. While this was a pilot study, it suggests more information is needed to understand how to effectively impact the patient's knowledge and subsequent self-management of CKD.

Lederer et al. (2015) conducted a qualitative study to evaluate the effectiveness of communication between veterans, diagnosed with CKD, and their healthcare providers. The population included veterans over the age of 18 with a history of CKD, on dialysis, or those with a kidney transplant treated at a Veterans Affairs' (VA) nephrology clinic. A total of 32 patients participated in the qualitative study, which used semi-structured interviews conducted via telephone to understand the patients' needs when it comes to kidney education. The interview included 17 open- and 15 closed-ended questions regarding the patient's experiences with their provider during their nephrology visits. Ninety-one percent of the patients reported limited information regarding their CKD and reported needing more information. Important themes that emerged from this study related to potential communication barriers between the patient and the provider: patients perceived themselves as being the "listener," baseline CKD knowledge was limited, patients did not understand the information provided, dissatisfaction with the patient-provider relationship, and patients felt their feedback was perceived by the provider as "passive" (Lederer et al., 2015, p. 768). While this study had a relatively small size, it did identify barriers that needed to be considered when conducting an educational intervention. Additionally,

patients wished for more information and believed a lack of information prevented them from making informed decisions (Lederer et al., 2015). Given the complicated arc of this disease process, a lack of the patient's understanding of the disease process may result in worsening kidney disease, non-adherence to medication and dietary recommendations, and inadequate preparation for ESRD treatment (Lederer et al., 2015). The patient with CKD-IV requires an enormous amount of information to effectively manage his or her disease process, emphasizing the importance of effective provider communication during the education class (Lederer et al., 2015). This study helps identify the need for establishing interventions to improve patient education and evaluate the effectiveness of that education.

Theoretical Framework

The theoretical framework for this study was the Health Belief Model (HBM). The HBM was developed in the early 1950s to predict and explain how patients perceive their health behaviors and subsequently predict patient adherence to recommendations (Rosenstock, Stecher & Becker, 1988). The underpinning for the HBM is the patient who develops health behaviors defined by his or her personal beliefs and perceived threats from his or her medical condition (Rosenstock et al., 1988). For patients with chronic illnesses, such as CKD, incorporating long-term changes may be quite challenging and requires a strong commitment from the patient (Rosenstock et al., 1988). According to the HBM, in order to commit to long-term changes, the patient must have an incentive to make the change, perceive a physical threat by his or her current medical condition, and recognize that making a change may be beneficial (Rosenstock et al., 1988). Given those three ingredients, the HBM predicts that patients will be more likely to engage in activities to improve their health (Jones et al., 2015).

The HBM model focuses on six core concepts 1) perceived susceptibility, 2) perceived severity, 3) perceived benefits, 4) perceived barriers, 5) cues to action, and 6) self-efficacy (Becker & Janz, 1985; Rosenstock et al., 1988). By centering education around the perceived susceptibility, perceived severity and the perceived benefits concepts, the provider was able to think about the types of behaviors that are necessary to assist a patient in changing his or her behavior to prevent the progression of CKD to ESRD. When considering education, helping the patient understand the probability of progression of CKD-IV to ESRD by identifying the signs and symptoms will promote the patient's susceptibility. Helping educate the patient about the consequences of the disease process (severity) and informing the patients of the benefits of delaying progression are essential to empower the patient to make beneficial changes to his or her health behavior. Consequently, utilizing the HBM allowed the researcher to promote shared decision making and stimulate the patient towards adopting appropriate health behaviors (cues to action). The results of this study provided opportunities to identify the specific areas, based on the HBM concepts and study findings, that may require an intervention in order to improve the effectiveness of the education class (Rosenstock et al., 1988). This model helped develop effective educational interventions to advance compliance interventions and slow the progression of CKD.

Identifying and Defining Study Variables

The independent variable of this study was the standardized CKD education class delivered to the individual patient. The dependent variable of this study, patient kidney knowledge, was measured by utilizing the KiKS survey (refer to Appendix B for the study variable table). The KiKS questionnaire has a total of 28 questions. Five questions are multiple choice and 23 questions have binary yes/no options. The questionnaire has a maximum score of

28 points. One point was given to each correct answer and zero was attributed to a wrong answer; thus, scores ranged from zero to 28 with a higher number demonstrating a higher level of knowledge (Mota-Anaya, Wright-Nunes & Mayta-Tristan, 2016).

Patient demographic data was also collected including the patients' age, gender, race/ethnicity, level of education completed, marital status, and self-reported overall health status (refer to Appendix C).

Methods

Research Design

This study design was a pilot, one-group pre and post-test design in which participants with CKD-IV participated in a standardized education class. Each participant completed a KiKS questionnaire before they attended the class and then completed the same KiKS questionnaire immediately after the education class. This design was selected given the information was collected at two points in time, based on questionnaires, and was easy to complete given this study's time frame limitation. This design provided the investigator a better understanding of the relationship between CKD-IV and a standardized education class. Additionally, it supports an opportunity to repeat in the future and further evaluate trends associated with CKD-IV and education within this particular clinic (Sedgwick, 2014).

Approval from The George Washington University (GWU) Institutional Review Board (IRB) was received. Furthermore, written permission was received from the privacy officer at the renal clinic where the study was performed. Written informed consent was obtained from all of the study participants (refer to Appendix D for a copy of the informed consent).

Sample and Setting

Census sampling was used to recruit the study participants. The study participants were patients at one urban, physician-led group practice associated with an academic medical center. This practice is staffed by six nephrologists, two NPs, three nephrology fellows and three research staff members. The renal clinic provides comprehensive care to patients with various acute and chronic kidney disorders, and cares for patients in the inpatient and outpatient setting serving patients residing in the metropolitan area of Washington, D.C. including Northern Virginia and portions of the State of Maryland.

The inclusion criteria for this study included: (a) adult patients (male and female), 18-89 years of age; (b) established CKD-IV, as defined by the NKF-KDOQI; and (c) patients who spoke English. The exclusion criteria included: (a) patients at earlier stages of CKD (i.e. CKD Stages I, II or III); (b) patients currently on hemodialysis; (c) patients cognitively or visually impaired; and (d) non-English speaking patients.

Sample Size

Using a two-tailed hypothesis, a minimum of 52 subjects was required. This estimation was obtained given the probability level (p value) of 0.05, a large anticipated effect size (Cohen's $d = 0.8$), and a desired statistical power of 0.8 (Soper, 2017). However, since this was a pilot study with a limited time frame, the study enrolled a total of 14 subjects.

Recruitment of Subjects

The method for recruitment of potential subjects consisted of referrals from the six nephrologists. The investigator informed the renal team of the goals of the study, including the inclusion/exclusion criteria. The investigator screened the patients in the CKD education clinic for eligibility through the medical record based on the inclusion/exclusion criteria. The patients

that met eligibility were invited to participate in the study prior to his/her appointment.

Additionally, recruitment flyers were posted in prominent areas within the renal clinic (refer to Appendix E for the recruitment flyer).

In order to mitigate the risk of attrition, the investigator informed the study participants that no additional clinic visits were required to complete the study. All participants were informed that everyone received the same intervention despite participation in the study. All participants were provided privacy and a comfortable space to complete the questionnaires. All participants were asked, "How comfortable do you feel answering medical questionnaires?" For persons that did not feel comfortable, the investigator did not proceed with the study.

Intervention

In 2006, Congress mandated the Centers for Disease Control and Prevention (CDC) to identify public health strategies aimed at preventing associated complications of CKD and work towards delaying the disease in those patients with CKD (Enworom & Tabi, 2015). The CDC recognized that lack of public awareness contributed to CKD and recommended public education (Enworom & Tabi, 2015). In 2008, MIPPA focused on ways to slow the progression of CKD and to improve the care for patients with ESRD (Enworom & Tabi, 2015). Additionally, MIPPA allowed for renal providers to provide reimbursable educational services to Medicare patients, in CKD-IV, in order to promote patient education (Enworom & Tabi, 2015). Subsequently, the NKF developed a curriculum, *Your Treatment, Your Choice*, aimed at providing educational tools consistent with the requirements as set forth by the MIPPA (NKF, 2012). In tandem with the aim of the MIPPA, the NKF patient-centered education curriculum emphasizes content related to the prevention of CKD complications, the progression of the disease process, and the various options available for ESRD treatment (NKF, 2012). The curriculum is recognized to

provide a more realistic approach to patient goal setting and support for self-management of CKD (Hemmett & McIntyre, 2017).

Each subject participated in the formal education class that was held within the renal clinic and lasted approximately 60 minutes. To enhance the reliability and validity of the study, the education class was performed by one NP in an attempt to reduce the potential for inconsistent delivery of the intervention that comes from multiple instructors. There was no control or comparison/intervention group.

Instruments and Measurements

Two different instruments were utilized to collect data during this study: (a) a self-administered demographic questionnaire; (b) a self-administered KiKS paper and pencil questionnaire.

A brief demographic screening tool was completed by subjects prior to their participation in the education class. Items reflected age, gender, race/ethnicity, marital status, level of education completed, and overall health status.

The KiKS was designed to evaluate the subjects' understanding of kidney disease-specific knowledge, and was completed by the subject in writing. The KiKS was administered (a) once before the intervention, and (b) then immediately after the intervention. The KiKS has been previously examined for adequate reliability and validity. The KiKS tool was developed and tested on 406 patients at one nephrology clinic to assess the kidney knowledge in pre-dialysis patients (Wright et al., 2011). Their results were analyzed for internal consistency and the Kuder-Richardson-20 reliability coefficient was 0.72 (Wright et al., 2011). Additionally, the mean score for the KiKS was 0.66 +/- 0.15 with a range of 0.11-0.96 (Wright et al., 2011). Wright et al. (2011) also purport that the KiKS tool adequately characterizes the areas of poor

kidney knowledge and provides awareness of critical topics that may need to be addressed when monitoring the effectiveness of CKD educational programs.

The KiKS survey has a total of 28 factual questions. Five questions are multiple choices and 23 questions are yes/no. One point was assigned to each correct answer; thus, a total of 28 points was the maximum score possible with a higher score associated with a higher kidney knowledge. Prior to and immediately after the education class, each subject was asked to complete the KiKS paper and pencil survey.

Data Collection Procedure

The investigator screened the patients scheduled in the CKD education clinic for eligibility through the medical records based on the inclusion/exclusion criteria. Patients that were identified as eligible were invited to participate in the study prior to his/her scheduled class.

No subject identifiers were included on the questionnaires. Each questionnaire was examined for completeness by the investigator and subject prior to its collection by the investigator. If a questionnaire was found to have an incomplete response, the questionnaire was returned to the study participant, and the study participant was asked to answer the incomplete question(s).

The pre questionnaires were collected by the investigator, who also conducted the education class, prior to the beginning of the intervention, and placed in a secure binder. Additionally, the post questionnaires were collected and placed in the same binder. That binder was kept by the investigator during the intervention. The binders were maintained securely locked in an office in the renal clinic's office throughout the course of the study period.

Data Analysis Plan

The investigator conducting the study entered the data into SPSS Statistics® and the data was checked for accuracy after entry and before analysis. The statistical software was stored on a password-protected computer in the renal clinic's administrative office. Once the data was entered into the password-protected statistical software, the paper questionnaires were disposed of within the locked security cabinet where medical documentation are maintained until regularly scheduled shredding occurs.

Descriptive statistics were used to summarize the sample – that is, respondents' characteristics (e.g., age, gender, race/ethnicity, marital status, level of education, and overall health status). In order to analyze the KiKS questionnaires, the data was first inspected visually and tested for normality of distribution utilizing the Shapiro-Wilk test. The Wilcoxon Signed-Ranks test was used to determine whether the mean kidney disease specific-knowledge was the same when measured at two different points: (a) before the standardized education class; and (b) immediately after the class. The distribution, central tendency, and dispersion of the pre and post scores were calculated and summarized after carrying out the Wilcoxon Signed-Ranks test.

Ethical Considerations

Each subject was asked to participate on a voluntary basis and was counseled that withdrawal was permitted at any time. In order to ensure the patient's right to autonomy was protected, written informed consent was obtained (Fouka & Mantzourou, 2011). The investigator provided clear and specific communication regarding the intent of the study and conducted the study in a consistent manner in order to report all data accurately.

Respect for privacy was safeguarded by maintaining anonymity and providing a private room to conduct the surveys and perform the intervention. Only the investigator had access to

the questionnaires completed by the subjects and the data was coded to be certain confidentiality was maintained. No identifiable data was placed on any of the questionnaires. The questionnaires were maintained in a locked and secure office within the renal clinic’s administrative offices until the data analysis was completed. After the data analysis was completed, all paper questionnaires were disposed of in a locked, secure shredder located within the renal clinic’s administrative office.

Results

Study Participants Characteristics

A total of 14 participants participated in this study. The study participant’s ages ranged from 43 to 78 years of age. Overall, the mean age of the study participants was 63 years. Sixty-four percent of the participants were female and 36% male. Of the participants, 79% identified themselves as Black/African American, 14% identified as white, and 7% chose other. Additionally, 21% were married, 36% were not married, 29% were widowed, and 14% were divorced. Forty-three percent reported having a high school or GED equivalent degree, 14% had some college and 43% were college graduates. Most of the participant’s (43%) rated their overall health as good. Refer to Table 1 for a complete presentation of the study participant’s characteristics.

Table 1

Characteristics of Study Participants

Characteristic	Range	Median	Description	Percentage
Age	43-78 years	63 years		
Gender			Female	64
			Male	36
Race/Ethnicity			Black/African American	79
			White	14
			Other	7

Marital Status	Married	21
	Not Married	36
	Widowed	29
	Divorced	14
Education Level	High School/GED	43
	Some college	14
	College graduate	43
Overall Health Status	Poor	14
	Fair	36
	Good	43
	Very Good	7

KiKS Questionnaire Results

First, in order to test the data for normal distribution statistically, the Shapiro-Wilk test was conducted. After carrying out the Shapiro-Wilk test, the pre-KiKS results demonstrated normal distribution of the data ($p = 0.546$), but the post-KiKS results demonstrated the data was not normally distributed ($p = 0.001$). Since it was not possible to assume normality of the data distribution, a non-parametric test, the Wilcoxon Signed-Ranks test, was selected in order to compare the pre and post KiKS questionnaires as answered by the study participants. The Wilcoxon Signed-Ranks test showed that the post-KiKS scores were significantly higher than the pre-KiKS scores ($Z = -3.299$, $p = 0.001$). So, these results suggest that a standardized education class had a statistically significant positive impact on the patient's basic kidney disease-specific knowledge. Specifically, a formal, standardized education class will benefit persons with CKD-IV.

Discussion

The purpose of this pilot study was to evaluate the effectiveness of a standardized education class to persons in CKD-IV. Given the large-scale impact CKD is having on the health of persons in the U.S., slowing the progression of CKD by empowering patients with knowledge about ways to delay the progression of the disease process and ensuring patients are informed of

the various renal replacement modalities is vital (Mehrotra et al., 2005). The results of this study support the role education has in promoting a patient-centered approach in caring for the person with CKD (IHI, 2017).

A characteristic of this study that is thought-provoking is the benefit associated by conducting it within this particular renal clinic. This renal clinic fundamentally supports the MIPPA education benefit for Medicare-eligible persons that have been diagnosed with CKD-IV, and offers qualified providers the opportunity to schedule 60-minute patient appointments solely focused on CKD education. As pointed out by Zuber and Davis (2013), this reimbursable Medicare benefit is underutilized; thus, the findings of this study support the importance of ensuring educational opportunities are available for the CKD-IV population. Often times, both primary care and nephrology settings have reported that clinic time and clinic space are barriers to offering patients CKD education classes (Wright-Nunes, 2013). However, studies continue to suggest that pre-dialysis education may strongly benefit the patient in delaying the progression of the disease process; still, barriers do exist that may limit access to this resource (Wright-Nunes, 2013). Yet, given the increase in the number of NPs within specialty fields, such as nephrology, NPs should take advantage of filling an educational gap by increasing access to pre-dialysis education for persons in CKD-IV (Zuber & Davis, 2013).

The post KiKS scores were higher than the pre KiKS scores which supports the fact that when working towards improving the effectiveness of the information provided to persons in CKD-IV, a standardized education class is necessary. Furthermore, this education goal is supported by the Medicare-sponsored educational benefits, and consequently, offers qualified providers a financial incentive (NKF, 2015).

A large percentage of the study participants reported their overall health status as “good” (43%). This may suggest that persons with CKD-IV lack an understanding of how important the state of their overall physical health is when aiming to slow the progression of CKD-IV to ESRD. Providing patients with effective education has an important role in improving patients’ choices and decisions that may impact their overall health status. This is especially significant for a person with CKD-IV as the individual must understand the perceived threat CKD-IV poses to his/her overall health in order to make the necessary changes and ultimately delay ESRD (Rosenstock et al., 1988).

Providing effective education is important for the person with CKD-IV, and this study helps to support the benefit of a standardized education class.

Study Limitations

There were several limitations related to this study. First, this was a pilot study that did not offer a comparison group; hence, external factors may have impacted the study participant’s kidney knowledge. For example, it is possible the study participant may have tried to remember the questions from the pre questionnaire since the study participant knew he/she would be answering that same questionnaire at the end of the standardized education class. Additionally, while this study utilized one NP to conduct the class in order to deliver consistency, there is a possibility the investigator emphasized important parts of the class based on the investigator’s knowledge of the study questions that would be assessed. Another potential external factor may be related to the referring nephrologist. Therefore, it would be important to account for the differences amongst the referring nephrologists based on how much education individual nephrologist’s provided to his/her patients prior to referring the patient to the CKD education clinic.

The small sample size is another limitation that challenges the real effect from the standardized education class versus possible effects from random variations. Additionally, the KiKS questionnaire was lengthy and may have been a barrier for recruiting study participants that did not want to complete a lengthy questionnaire. While an appealing characteristic of this study was the fact the pre and post questionnaires were collected at the time of the patient's visit, this also limits understanding the study participant's knowledge retention over a longer period of time. Lastly, another limitation of this study is that all study participants were recruited from one urban renal clinic, and consequently, generalizability is limited.

Implications/Recommendations

This pilot study provides important implications for the nursing practice. For the general population, kidney disease awareness remains limited; therefore, developing effective practices, such as standardized education classes within nephrology clinics and primary care settings, is essential in improving patient knowledge (Lederer et al., 2015). Since the person in CKD-IV is at the greatest risk for developing ESRD, improving basic kidney knowledge, such as in the form of a standardized education class, to the patient in CKD-IV is invaluable (NKF, 2015).

Understanding knowledge retention is important. Therefore, further research evaluating the participant's knowledge at longer intervals in order to explore how study participants retained the information provided in the standardized education class. Also, given the small sample size of this pilot study, further research is needed to support the findings of this study using a larger sample.

While this study's standardized education class was provided on an individualized basis, future research could be done on the effectiveness of a standardized education class within a group setting. Since the reimbursable education benefit provided by Medicare allows qualified

providers to bill with for a group kidney disease education visit, it may be appropriate for future research to explore the impact a standardized education class would have on persons within a group setting (NKF, 2015).

Historically, an important role for NPs is providing patient education. Further research may be needed to explore whether similar outcomes would be obtained if a registered nurse provided a similar education class. However, it is important to note that for the Medicare-reimbursable incentive, as MIPPA currently stands, the person conducting the education class must be a Medicare-qualified provider. Nevertheless, the individual conducting the education class must have the necessary knowledge and skills to conduct the class, and perhaps further studies may be conducted in order to expand the type of qualified providers that are eligible to bill for this Medicare service.

It is difficult to fully understand the long-term impact a standardized education class has on the patient's health outcomes. Consequently, research should focus on the association between education and long-term health outcomes on a patient with CKD-IV. Also, it is possible that many renal clinics are not able to provide education classes secondary to the lack of qualified staff and the challenges associated with allocating clinic time and clinic space to implement the education classes. However, if more studies were conducted to demonstrate the improvements in clinical outcomes associated with educating the person with CKD-IV, perhaps more practices, both primary care and nephrology, would appreciate the value of including education classes within the plan-of-care for persons with CKD.

Efforts to promote patient education is an opportunity to empower the patient to speak on his/her behalf. It is important to utilize the current education benefit provided by Medicare, and then contribute to the studies that demonstrate the behavioral changes education promotes on

persons with CKD-IV. Therefore, more studies demonstrating the positive benefit of education may be effective in expanding the current Medicare-eligible benefit for persons in other stages of CKD so they may be provided similar education benefits.

Despite the aforementioned limitations, in this pilot study, it was demonstrated that for persons in CKD-IV, there was a positive benefit from attending a standardized education class. Providing effective standardized education classes will likely foster a partnership between the patient and provider that is essential when aiming to actively engage the patient to participate in his/her care.

Conclusions

In conclusion, kidney disease-specific knowledge is lacking amongst persons diagnosed with CKD-IV (Wright et al., 2011). Thus, a standardized approach to providing education will provide persons the opportunities to improve their basic understanding of kidney disease. With the support of tools, such as the NKF's *Your Treatment, Your Choice* curriculum, health care providers should incorporate standardized classes into their practice. Importantly, with the financial incentive offered by MIPPA, every nephrology provider should be empowered to offer kidney disease-specific education. Moreover, every nephrology provider should aim to bridge the communication gap between the provider and the patient by using education to promote a patient-centered approach in a complex shared decision-making process.

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Appendix A

Kidney Knowledge Survey (KiKS)

Item	
1. On average, your blood pressure should be: 160/90 150/100 170/80 Less than 130/80	Circle the correct answer
2. Are there certain medications your doctor can prescribe to help keep your kidney(s) as healthy as possible?	Yes or No
3. Why is too much protein in the urine not good for the kidney? It can affect the kidney It is a sign of kidney damage It can affect the kidney and is a sign of kidney damage It can cause a urinary infection All of the above	Circle the correct answer
4. Select the ONE MEDICATION from the list below that a person with CHRONIC kidney disease should AVOID: Lisinopril Acetaminophen/Tylenol Ibuprofen/Motrin Vitamin E Iron supplements	Circle the correct answer
5. If the kidney(s) fail, treatment might include (FOR THIS QUESTION you can PICK up to TWO ANSWERS): Lung biopsy Hemodialysis Bronchoscopy Colonoscopy Kidney transplant	Circle the correct answer
6. What does "GFR" stand for? Glomerular Filtration Rate Glomerular Flow Time Total Glomerular Flow Glucose Rate Function	Circle the correct answer
7. Are there stages of CHRONIC kidney disease?	Yes or No
8. Does CHRONIC kidney disease increase a person's chances for a heart attack?	Yes or No
9. Does CHRONIC kidney disease increase a person's chance for death from any cause?	Yes or No

10. Does the kidney make urine?	Yes or No
11. Does the kidney clean blood?	Yes or No
12. Does the kidney help keep bones healthy?	Yes or No
13. Does the kidney keep a person from losing hair?	Yes or No
14. Does the kidney help keep red blood cell counts normal?	Yes or No
15. Does the kidney help keep blood pressure normal?	Yes or No
16. Does the kidney help keep blood sugar normal?	Yes or No
17. Does the kidney help keep potassium levels in the blood normal?	Yes or No
18. Does the kidney help keep phosphorus levels in the blood normal?	Yes or No
19. Increased fatigue?	Yes or No
20. Shortness of breath?	Yes or No
21. Metal taste / bad taste in the mouth?	Yes or No
22. Unusual itching?	Yes or No
23. Nausea and / or vomiting?	Yes or No
24. Hair loss?	Yes or No
25. Increased trouble sleeping?	Yes or No
26. Weight loss?	Yes or No
27. Confusion?	Yes or No
28. No symptoms at all?	Yes or No

Appendix B

Study Variable Table

Variable Name	Variable Type and Form	Theoretical/Descriptive Definition	Operational Definition
Patient's CKD-IV kidney knowledge	Dependent Interval		As measured by the Kidney Knowledge Survey (KiKS). 1 point for each correct answer (for a total of 28 points)
Standardized education class for patient's diagnosed with CKD-IV	Independent	Patient will receive a 60-minute standardized, individualized CKD-IV education class utilizing the NKF <i>Your Treatment, Your Choice</i> curriculum	0 = before intervention 1 = after intervention
Patient self-reported overall health status	Demographic/Explanatory Ordinal	Patient self-report of overall health status	1 = poor 2 = fair 3 = good 4 = very good 5 = excellent
Age	Demographic Interval/Count	Patient report of age in years	Patient age in years 18 to 89
Gender	Demographic Categorical	Patient report of gender	1 = male 2 = female 3 = N/A
Race/ethnicity	Demographic Categorical	Patient report of race/ethnicity	1 = black/African American 2 = white 3 = other
Marital status	Demographic Categorical	Patient report of marital status	1 = married 2 = not married 3 = widowed 4 = divorced 5 = separated
Education	Demographic Categorical	Patient report of education completed	1 = high school diploma/GED or less 2 = some college 3 = college graduate

Appendix D

Informed Written Consent

Education and the Impact on Chronic Kidney Disease
IRB # 081731

Principal Investigator: Michelle Rumble, DNP, RN, MPH 571-553-4493

Primary Contact: Nancy Uhland, MSN, NP-C 202-741-2283

Sponsor: The George Washington Medical Faculty Associates (MFA) Renal Division

You are invited to take part in a research study under the direction of Michelle Rumble, DNP, RN, MPH of the Department of Nursing at The George Washington University. While Dr. Rumble is the Principal Investigator, Nancy Uhland, MSN, NP-C at The George Washington University Medical Faculty Associates (MFA) renal division will conduct the study's interventions. The purpose of this study is to evaluate the effectiveness of an education class on patients' knowledge of their chronic kidney disease.

You are being asked to take part in this study because your kidney doctor has diagnosed you with chronic kidney disease and has referred you to the education clinic. Please read this form and if you have any questions, please ask. Taking part in this study is completely voluntary and you may choose to quit at any time.

All patients referred to the kidney education clinic will be considered for participation; however, you must be at least 18 years of age or older to participate in this study.

Your decision to participate will not impact any care you receive at the MFA kidney clinic. All patients referred to the education clinic will receive the same information/class regardless of their participation in the study.

You will be asked to complete a medical questionnaire. On the front page of the questionnaire, there will be 6 demographic questions and then 28 questions about kidney function and kidney disease prior to the education class. This will take approximately 20 minutes to complete. Then after the education class, you will be asked to answer the same questionnaire about kidney function and kidney disease and should take less than 20 minutes. In total, the amount of time you will spend in connection with this study is approximately 35 minutes. This one visit is all that is required to participate in the study.

Considerable effort will be taken to ensure that your name cannot be associated with your answers on the questionnaire; however, there is the possible risk of loss of confidentiality. The following steps are being taken to reduce this risk: completion of the questionnaires and participation in the education class will occur privately; no identifiable data will be placed on any questionnaire; only the investigators will have access to the questionnaires completed by you and the data will be coded to be certain that confidentiality is maintained; the paper questionnaires will be locked security cabinet locked in a drawer located within the

administrative office of the MFA renal division and disposed of (shredded) after data analysis has been completed; you will not be asked to place your name, date-of-birth or any personal identifiers on the questionnaires; computers and files used for analysis of the data will be on a password-protected computer; in any published articles or presentations, information will be presented in aggregate; no information will be published that will make it possible to identify you as a subject.

Your records for the study may be reviewed by Michelle Rumble and Nancy Uhland and members of the departments of the University responsible for overseeing research safety and compliance.

Results of this research study may be reported in journals or at scientific meetings. Information will be presented in aggregate and no information will be published that will make it possible to identify you as a subject. GWU will not release any information about your research involvement without your written permission, unless required by law.

You will not benefit directly from your participation in the study; however, your participation will benefit science and humankind by contributing new knowledge, which could positively influence the nursing care and patient education provided to those with chronic kidney disease.

Talk to the research team if you have questions, concerns, complaints, or think you have been harmed. You can contact the Principal Investigator listed on the front of this form at 571-553-4493 or Nancy Uhland at 202-741-2283. For questions regarding your rights as a participant in human research call the GWU Office of Human Research at 202-994-2715.

If you agree to take part in this study, please sign below. After you sign this consent form, the research team will provide you with a copy. Please keep it in case you want to read it again or call someone about the study.

Your printed name: _____

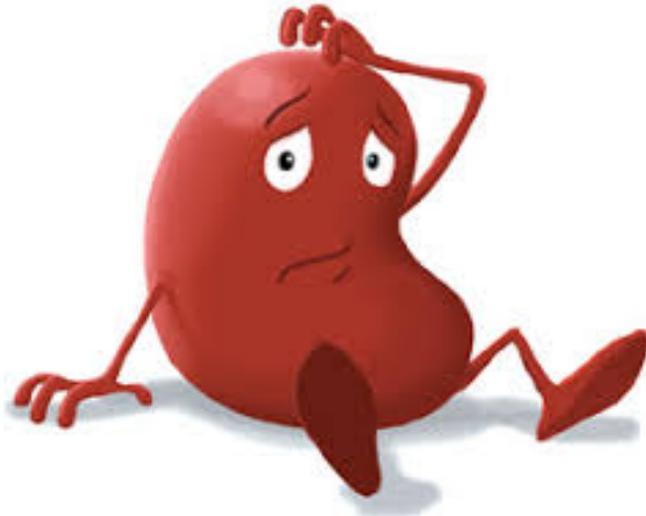
Your signature: _____

Today's date: _____

Appendix E

Recruitment Flyer

Study participants needed in the CKD education clinic...



Please consider referring your patients to the CKD education clinic. This is a study that will explore the impact education has on the pre-dialysis patient's kidney knowledge before and after a standardized education class.

Who do we need?

Participants who are 18 years of age or older and diagnosed with CKD-IV
English speaking

CONTACT FOR MORE INFORMATION: Nancy Umland, NP-C
202-741-2283
nuhland@mfa.gwu.edu

