2017

Demographic Factors That Correlate with Adherence to Hemodialysis Treatment Regimen

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Demographic Factors That Correlate with Adherence to Hemodialysis Treatment

Regimen

by

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A thesis submitted to the faculty of
Gardner-Webb University Hunt School of Nursing
in partial fulfillment of the requirements for the
Master of Science in Nursing Degree

Boiling Springs, North Carolina

2017

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Abstract

Background: Research has shown that non-adherence to the recommended treatment regimen in patients with chronic health conditions such as end stage renal disease can have detrimental consequences such as cardiac enlargement, difficulty breathing, cardiac arrest, and death. Several studies have shown a patient's age, marital status, gender, and family support can affect adherence to treatment regimen in hemodialysis patients. Purpose: The goal of this study was to provide insight into the demographic factors that correlate with adherence to treatment regimen in hemodialysis patients. Method: This research study consisted of a retrospective chart review of 75 charts of chronic outpatient hemodialysis patients in two freestanding hemodialysis clinics in a midsized city in the southeastern United States. Using a chart audit tool, developed by the researcher, the following information was collected for this study: treatment attendance (three days per week), including shortening treatment, adherence to fluid restriction, and potassium and phosphorus values. The following demographic information was also collected for this study: age, race, cause of ESRD, gender, marital status, and hemodialysis vintage (how long a patient has been on hemodialysis). Results: The results indicated that treatment attendance was positively associated with being married. Conclusion: This study suggested that patients who lack spousal support may be more at risk of non-adherence to treatment attendance than patients who are married.

Key words: patient adherence, hemodialysis patients, Roy's Adaptation Model, adaptation, hemodialysis.

Acknowledgments

I want to thank my family for their love and support, especially my sweet little doggies Benson and Ellie.

TABLE OF CONTENTS

List of Tables

CHAPTER I

Introduction

Patients with end stage renal disease (ESRD) must adapt to the multitude of changes that come with the diagnosis in order to attain their personal highest level of function and be free from uncomfortable, possibly life-threatening complications. When a patient is diagnosed with ESRD, they are thrown into a whirlwind of dietary and fluid restrictions, multiple medications, lifestyle changes, and a great deal of education. Some patients achieve adaptation while others are unable to or struggle to do so.

According to Alikari and Zyga (2014), in the management of chronic diseases such as diabetes mellitus, cardiac or renal insufficiency, adherence may decrease fatality rates. Failure to follow health instructions has both a direct and an indirect impact on the individual and society. Non-adherence increases mortality and the use of health services, resulting in a decrease in productivity through lost working hours and increase of the cost of health services. Factors that may be attributed to non-adherence include personal characteristics, such as dementias, lack of willingness or low educational level (Alikari & Zyga, 2014). According to Martin, Williams, Haskard, and DiMatteo (2005) a significant barrier to effective medical treatment is patient failure to follow the recommendations of physicians or other healthcare providers. Patient nonadherence, or noncompliance, includes misunderstanding, orders being carried out incorrectly, forgotten, or ignored. Non-adherence to potassium intake in hemodialysis patients can lead to cardiac arrest and death (Cicolini, Palma, Siminetta, & Di Nicola, 2012). High phosphorus levels pull calcium out of the bones, making them weak and can lead to dangerous calcium deposits in blood vessels, lungs, eyes, and heart (National Kidney Foundation, 2016a). If patients

do not control their fluid intake it can lead to fluid overload which can result in hypertension, difficulty breathing, and can increase the size of their heart (National Kidney Foundation, 2016b). According to Reach Kidney Care (2015), if a patient misses one dialysis treatment a month they have a 14% higher risk of dying and if they miss more than one treatment a month they have a 27% increased risk of dying.

The population of patients receiving dialysis is a group of individuals that would greatly benefit from solutions to multiple care problems, one of which being treatment adherence. In the state that serves as the research setting for this study, there are approximately 92 dialysis clinics. According to the United States Renal Data Systems (USRDS) (2015), in the year 2013 alone there were 421,349 patients receiving hemodialysis in the United States. A study conducted by Mellon, Regan, and Curtis (2013), designed to assess the predictive value of demographic and psychological variables in non-adherence in hemodialysis patients, found that 62% of the participants were nonadherent with at least one aspect of the treatment regimen.

Purpose

This study provided insight into the demographic factors that correlate with adherence to treatment regimen in hemodialysis patients. Members of the interdisciplinary care team can utilize the findings to better support nonadherent patients in their adaptation process so they can achieve adherence with their recommended treatment regimen. The results of this study can be used by nephrology nurses to develop a new process for assisting patients to adapt to living with end stage renal disease. By recognizing that patients with certain demographic criteria may be more at risk of

treatment non-adherence, nurses can proactively support these patients through education and building a therapeutic relationship.

Research Question

What demographic factors correlate with adherence to hemodialysis treatment regimen? For this study, patient adherence focused on treatment attendance (three days per week) for each of the weeks included in the reviewed month, including shortening treatment and adherence to fluid restriction. Adherence to fluid restriction was defined as a patient is gaining three kilograms or less between treatments. Lab values for potassium and phosphorus were collected and evaluated to determine if the results were within normal ranges. The following demographic information was also collected for this study: age, race, cause of ESRD, gender, marital status, and hemodialysis vintage (how long a patient has been on hemodialysis).

Theoretical Framework

Roy's Adaptation Model (RAM) provided the theoretical framework for this research study to investigate what demographic factors correlate with adherence to hemodialysis treatment regimen. Butts and Rich (2011) described the RAM as a theory grounded in the premise that the world is composed of interconnected systems influenced by one another (as cited in Shultz & Hand, 2015, p. 67). Roy began work on the RAM in 1960 during her Master's education when she sought to answer a simple yet complex question, "describe the goal of nursing", her response was "to promote adaptation" (as cited in Clarke, Barone, Hanna, & Senesac, 2011, p. 337). The major concepts identified by RAM are adaptation, person, environment, health, and goal of nursing. Roy defines adaptation as "the process and outcome whereby thinking and feeling persons, as

individuals, or in groups, use conscious awareness and choice to create human and environmental integration" (Shultz & Hand, 2015, p. 68).

Roy states that as living systems, all people are in constant interaction with their environments (Shultz & Hand, 2015). Environmental stimuli may be focal, contextual, or residual. Focal stimuli are described as internal or external and immediately confronting the person. Contextual stimuli are described as all stimuli present in a situation that contribute to the effect of focal stimulus. Residual stimuli are described as a factor whose effects in a situation are unclear. The management of these stimuli by individuals and groups of individuals affect adaptation. The two major adaptation mechanisms are the cognator and the regulator. The cognator subsystem is a coping process involving four channels: perceptual and information processing, learning, judgment, and emotion. The regulator subsystem responds automatically through neural, chemical, and endocrine coping channels (p. 68). According to Gonzalo (2011), Roy identified four adaptive modes: physiologic-physical mode, self-concept-group identity mode, role function mode, and interdependence mode. The three psychosocial and one physiologic mode influence each other and fulfill a need to maintain integrity within an individual or group (as cited in Shultz & Hand, 2015, p. 68). Shultz and Hand (2015) described the RAM as a predictive theory due to the fact that it specifies how a concept affects other concepts. Due to the various potential applications of the RAM, it has been used as a conceptual framework for multiple research studies and it has been adapted for use in a wide range of nursing practice areas.

CHAPTER II

Review of Literature

A review of current literature was conducted using the Cumulative Index to Nursing and Allied Health Literature (CINAHL) Plus with full text. Research articles were limited to full text, English language academic journals from 2011 to present. Key words used to search were "patient adherence", "hemodialysis patients", "Roy's Adaptation Model", "adaptation", and "hemodialysis". The search revealed 126 articles that were reviewed for inclusion in this research study. The following articles were selected based on their relationship to the chosen research topic. Furthermore, a review of current literature was conducted for research articles utilizing Roy's Adaptation Model.

Roy's Adaptation Model

Akyil and Ergüney (2013) conducted a quasi-experimental study comparing the effects of Roy's Adaptation Model based education in chronic obstructive pulmonary disease (COPD) patients in Turkey. This study was developed to aid in COPD patient adaptation to the disease. A 35-item survey developed by the researcher was based on three of the four RAM modes. Research questions developed for this study included the patient's beliefs regarding physiologic, physical, personal, and role-function changes related to living with COPD. Validity and reliability was established for this survey by the researcher consulting five academic nurses based on previously reported information about COPD. The internal consistency of the sub-scales of the form used for rating patient adaptation levels (physiological, self-concept, and role-function) was examined by computing Cronbach's alpha for each series of questions. Participants of this research study were patients in the outpatient clinics of the department for chest diseases of a

hospital in Turkey. The inclusion criteria were the diagnosis of COPD for six months or longer, residence in the city, absence of any additional disease diagnoses, the ability to read and write and willingness to participate in the study. There were 32 participants in the intervention group and 33 participants in the control group. Both groups completed the pretest and posttest, but the patients in the intervention group underwent a one-month period of training by the investigators using verbal education and an education booklet. The investigators organized the booklet following RAM and COPD literature. The patients in the control group also received posttests three months after the pretest. Following the posttest, the control group received the same educational booklet that the intervention group received and the relevant explanations, in consideration of patients' ethical rights. The results indicated that education given in accordance with Roy's Adaptation Model increased patient adaptation to disease (COPD) in three modes (physiologic, self-concept and role-function mode). The limitations of this study included the small number of participants and non-inclusion of patients with additional diagnoses. The results of this study revealed that patient education given in accordance with Roy's Adaptation Model increased patient adaptation to COPD as opposed to no additional education.

A descriptive, qualitative study conducted by Ordin, Karayurt, and Wellard (2013) investigated the adaptation of liver transplant recipients using Roy's adaptation model as the conceptual framework. Two instruments were used to gather information in this study. The first was a form developed by the researcher to gather demographic and liver disease/transplant information. The second was a form developed by the researcher to gather information related to how the participant is adapting to liver transplantation.

Research questions developed for this study included open-ended questions about how the participant felt physically and emotionally, effects of social roles, and social relations after liver transplantation. There were also open-ended questions regarding the support needs and knowledge needs of the participant, and the people who supported them during and after liver transplantation. Validity and reliability of the survey questions has not yet been established. Twenty-one patients were recruited from an outpatient transplant department at the university hospital in Turkey. Inclusion criteria were between 18 and 65 years of age, willingness to participate in the study, no record of psychiatric disease, native Turkish speaker, and experiencing their first transplant. Results revealed patients needed information and support regarding their ineffective behaviors in all modes of the RAM. The results indicated that health professionals must meet the information and support needs of patients.

A descriptive study conducted by Phillips (2011) used Roy's Adaptation Model to develop an instrument to measure the internalized stigma of AIDS. The purpose of this study was to measure the internalized stigma of AIDS so that nurses may better understand patient experiences to plan and deliver quality patient care. A 10-item instrument was developed to determine a person's stigmatizing beliefs related to the physical and personal self. The instrument addressed aspects such as how people feel about having AIDS, how having AIDS affects their interaction with others, and body image. According to Phillips (2011), two criteria are used to judge the usefulness of the most frequently used instruments in research guided by the Roy Adaptation Model: consistency with the model and adequacy of the psychometric properties. The author

recommended using the instrument in different settings and with other patient populations to further validate their findings.

Roy's Adaptation Model and Adherence

Hacihasanoğlu and Gözüm (2011) designed a randomized controlled study to investigate the effect of anti-hypertensive patient-oriented education and in-home monitoring on medication adherence and management of hypertension in a primary care setting using Roy's Adaptation Model as part of the theoretical framework. The sample consisted of 120 hypertensive patients diagnosed at least one year prior to the study, age 35 or greater, were prescribed antihypertensive medication, literate, able to communicate easily and cooperate with researchers and who did not have any other disease or condition. The participants were divided equally into three groups. Groups A and B received medication adherence education and group B also received education about healthy lifestyle behaviors. Group C (the control group) was routinely monitored in health care facilities. The following findings supported the hypothesis. Education in medication adherence and healthy lifestyle behaviors improved medication adherence in the study groups (Groups A and B) with a P value of 0.000. Education in medication adherence and healthy lifestyle behaviors resulted in lower average blood pressure values in study groups (Groups A and B) with a P value of 0.000. Medication adherence levels in study Group B (education in both medication adherence and healthy lifestyle behaviors) were higher than that of the patients in Group A (who received only medication adherence education) with a P value of 0.000. The average blood pressures of patients in study Group B who received education for both medication adherence and healthy lifestyle behaviors was better than the patients in study group A who received

only medication adherence education with a P value of 0.000 (Hacihasanoğlu & Gözüm, 2011, p. 698). According to Veliog ˘lu (1999), a subject's behavior is affected by their abilities in addition to internal and external stimuli (as cited in Hacihasanoğlu and Gözüm, 2011, p. 693). According to Hacihasanoğlu and Gözüm (2011), adherence education given by the nurse contributes to adaptation of the patients to their disease and to the therapy as an external stimulus. The researchers also suggested continued patient education regarding hypertension.

<div align="center">**Roy's Adaptation Model and Hemodialysis Patients**</div>

Frazão et al. (2014) designed a study identifying adaptation issues in patients undergoing hemodialysis and their correlation with socioeconomic and clinical aspects using Roy's Adaptation Model as a framework. The study sample consisted of 178 patients receiving dialysis at a chosen clinic in Brazil. The researchers developed a questionnaire that consisted of sociodemographic data, history of the current health problems, the hemodialysis treatment, the adaptation modes of Roy's Adaptation Model (physiological, self-concept, role function and interdependence), a general physical examination, and the patient's most recent laboratory results. The study revealed lower income, lower education level, and advanced age were found to be factors that had a negative influence on adaptation problems such as potassium level, edema, activity intolerance and role failure. Based on the results, the researchers determined clinical aspects do indeed correlate with adaptation problems in patients undergoing hemodialysis. The limitations of the study included a shortage of reported research on the topic and the limited population of only chronic hemodialysis patients.

A descriptive study conducted by de Queiroz Frazão, Bezerra, de Paiva, and de Carvalho Lira (2014) was developed to identify the changes in the self-concept mode of Roy's Adaptation Model in women undergoing hemodialysis. The study took place in a hemodialysis clinic in northeastern Brazil over a three month period in a hemodialysis clinic. A nephrology nurse conducted the interviews. The authors did not provide information regarding the types of question that the participants were asked. Of the 178 patients that were interviewed, 24 interviews of women were selected for analysis based on changes in the self-concept mode. Thirteen women stated they had sexual dysfunction and eight women stated they had low self-esteem and three women had both problems. Based on the results of this study, the authors recommended that nursing care plans focus on the adaptive problems of the self-concept mode. A limitation identified by the researchers was the focus of the study was only on the self-concept mode. The researchers recommended new studies that include all of the modes of Roy's Adaptation Model.

<div align="center">**Hemodialysis Patients and Adherence**</div>

Smyth, Hartig, Hayes, and Manickam (2015) conducted a retrospective chart review to quantify the number of patients who attended 100% of their scheduled hemodialysis sessions, and the number of patients who gained no more than one kilogram per day between dialysis sessions, over a three month period. The study took place in Australia. The sample consisted of the charts of patients scheduled to attend hemodialysis at the in-hospital renal unit from the week beginning March 4, 2013, and who underwent scheduled hemodialysis at the in-hospital unit for at least 50% of the 12-week data collection period. Exclusion criteria were the charts of patients who transferred out of the

unit within the 12 weeks, died or changed treatment modality to peritoneal dialysis, and charts that contained less than six weeks of data. Seventy-two charts met the inclusion criteria. A renal nurse collected the chart data. The results revealed 56.9% of patients attended all of their scheduled treatments. Regarding adherence to fluid allowances, on average approximately three quarters of the patients were able to adhere to the recommended daily weight gain. Limitations of the study included incomplete documentation and the inability to determine the reason the patients did not attend their treatments.

Nabolsi, Wardam, and Al-Halabi (2015) explored the relationship between quality of life, depression, perception of seriousness of illness, and adherence to treatment among Jordanian patients with end stage renal disease on hemodialysis. The researchers used a questionnaire to gather patient information. The questionnaire included demographic information, perceived seriousness of illness, and adherence to diet recommendations, fluid restriction, medication, and dialysis sessions. The researcher used a descriptive correlation design using a convenience sample of patients at four major hospitals in the city of Amman. The sample consisted of 244 patients. To be included in the study patients had to meet the following inclusion criteria: the participants had to be a dialysis patient at one of the four hospitals; 18 years of age or older; on dialysis for at least six months prior to the beginning of the study; confirmed diagnosis by a physician and the patient is under medical management; able to verbally communicate with researchers; able to be interviewed, and willing to participate in the study. Exclusion criteria were cognitive inability and significant comorbidities. The results revealed a moderate decrease in quality of life (QOL) in ESRD patients with a mean score of 20.086 and a

standard deviation of 3.34. Patients with higher QOL scores were more adherent to treatment regimen ($r = 0.20$, $P = 0.001$). The results also revealed a positive correlation between QOL and perceived seriousness of illness ($r = 0.34$, $P = 0.000$). The study also found that the more the patients perceive the seriousness of their illness the more they adhere to their therapeutic regimen and they had a higher QOL score. QOL and adherence ($r = 0.20$, $P = 0.001$) perceived seriousness of illness ($r = 0.34$, $P = 0.000$). Over half of the patients in the study reported moderate to severe depression using the Beck Depression Inventory. There was a negative correlation between depression and QOL ($r = −0.54$ $P = 0.000$). The limitations of the study were that only the Jordanian culture was studied and the sample only consisted of patients at four major hospitals in the city of Amman.

Oh, Park, and Seo (2013) designed a study to determine the psychosocial influencers and mediators of treatment adherence in hemodialysis patients. The study was performed using a non-experimental, cross-sectional design. The sample consisted of 150 patients receiving hemodialysis at a university hospital in Incheon, South Korea. The researcher used a questionnaire that consisted of self-efficacy on adherence, depression, treatment adherence, hemodialysis related knowledge, perceived barrier to adherence, family support, and healthcare provider support. The results revealed higher levels of knowledge and self-efficacy, a lower level of barrier and greater support from healthcare providers were found to promote adherence. Depression and family support were not found to have significant direct effects on adherence. Self-efficacy was found to have significant mediating effects on the relationship between barrier and adherence ($t=0.14$) and between family support and adherence ($t=2.70$). Self-efficacy was not found to

significantly mediate the relationship between knowledge and adherence and between healthcare provider support and adherence. Self-efficacy had a significant mediating effect on the relationship between depression and adherence. Hemodialysis-related knowledge (t=3.11), barriers to adherence (t=-3.06), self-efficacy on adherence (t=4.88), and healthcare provider support (=3.40) had significant effects on adherence. It was found that self-efficacy was the most influential factor of adherence. The researchers noted the limitation of the study was that it only provided information from the cross-sectional design.

Theofilou (2013) designed a study to explore the influence of depression and health cognitions on medication adherence among Greek hemodialysis patients. The study sample consisted of 168 patients from six hospitals in Athens. To be considered for inclusion in this study the participants had to be greater than 18 years of age; able to communicate in Greek; diagnosed with CKD; receiving dialysis for at least a year; and have an adequate level of cooperation and perceived ability. The researcher used a questionnaire that consisted of three instruments: the Medication Adherence Rating Scale, the Center for Epidemiologic Studies Depression Scale (CES-D), and the Multidimensional Health Locus of Control (MHLC) scale as well as demographic information. The results revealed medication adherence had a positive association with the dimensions of internal and doctor-attributed health locus of control, using the MHLC. Patients who were more adherent to medication demonstrated less symptoms of depression. Patients that were less than 45 years of age were significantly more adherent than patients that were greater than 45 years of age. Married patients showed significantly higher scores of medication adherence than patients that were single, widowed, or

divorced. The researcher noted the limitations of the study were that future studies should use prospective and longitudinal designs as well as a broader population of CKD patients and a larger sample size.

Sandlin, Bennett, Ockerby, and Corradini (2013) designed a study to explore the impact of a nurse-led education intervention on bone disorder markers, adherence to phosphate binder medication, and medication knowledge. The study used descriptive technique with a paired pre and post intervention survey. The study sample consisted of a convenience sample of patients in a metropolitan dialysis center in Australia. To be considered for inclusion in this study the participants must have received hemodialysis for more than one month and be 18 years of age and older. The final sample size was 62 patients. The patient's serum phosphorus, calcium, and parathyroid hormone (PTH) levels were drawn at baseline and at monthly intervals during the intervention period with the exception of the PTH, which was drawn at baseline and the third month. The pre and post intervention survey included which phosphate binder(s) they took and reported when they took their phosphate binders in relation to a meal (i.e. beginning, middle or end of meal) and a series of nine questions designed to explore their knowledge of phosphate binders and how to take them correctly. The nurses in the unit provided individualized education to the patients regarding their phosphate binders. The results revealed there were no significant changes in the patients' serum phosphorus, calcium, and parathyroid hormone (PTH) levels over the 12-week intervention period. There was a statistically significant improvement between the pre (44%) and post (72%) intervention surveys regarding the proportion of patients who took their phosphate binder correctly (at the beginning of a meal and not in the middle or the end) with a p-value of 0.016. The

researchers recognized the study limitations included the small sample size, the lack of a control group, the absence of tablet counting and food diaries, and the use of a non-validated survey. The researchers also recognized the potential for bias for patients who completed the survey verbally with assistance from a nurse.

Wileman et al. (2015) investigated the association between medication beliefs and depressive symptoms with non-adherence to phosphate binders in a group of hemodialysis patients. The study used a cross-sectional design. The study sample consisted of 112 patients from six hemodialysis units in the United Kingdom. To be considered for inclusion in this study the participants had to be prescribed phosphate binders, had a three-month average serum phosphate level of greater than 1.61 mmol/l, receiving dialysis for three months or more, able to read English, had not been hospitalized in the past three months, and not have other conditions that could possibly compromise short-term survival. The researchers collected data using four questionnaires the medication adherence report scale (MARS), the beliefs about medicines questionnaire (BMQ), patient health questionnaire PHQ-9, and a demographic questionnaire as well as gathering the patients' lab results from the electronic health record. The results revealed the mean baseline serum phosphorus level indicated inadequate phosphorus control. Necessity beliefs about phosphorus binders and concerns about phosphorus binders did not correlate. There were no significant differences between depressed and non-depressed patients regarding serum phosphorus levels. Patients' necessity beliefs about phosphorus binders was significantly associated with both adequate serum phosphate levels and patient self-reported adherence (Wileman et al., 2015). The researchers felt the

limitations of the study were the cross-sectional design and the models used did not account for the patients' residual renal function.

Ossareh, Tabrizian, Zebarjadi, and Joodat (2014) designed a study to evaluate medication adherence in hemodialysis patients and the correlation between quality of life and depressive symptoms. The study used a cross-sectional design. The study sample consisted of 150 patients in a kidney center in Iran. Exclusion criteria were patients who refused, or were unable to answer the questions due to advanced aged, advanced psychological problems, other than depression, or inability to communicate. The researchers collected data using four questionnaires. The Medication Adherence Questionnaire (SMAQ) and Drug Intake Percentage Questionnaire (DIPQ) were used to evaluate medication adherence. The Beck Depression Inventory (BDI) was used to assess depression. The Short Form-36 (SF-36) was used to assess quality of life. The patients' mean laboratory values for phosphorus, potassium, parathyroid hormone, and protein along with the interdialytic weight gain were collected from the medical charts during the past six months. The results revealed a negative correlation between the BDI and the SF-36. According to the SMAQ adherent patients were significantly older than nonadherent patients, had lower parathyroid hormone levels, and had lower BDI results. Nonadherence was more frequent in patients with depressive symptoms according to the BDI. The study found that older age was associated with adherence and the male sex was associated with nonadherence. The researchers felt the limitations of the study were the use of self-reported measures, such as the BDI; and the lack of a standard method of evaluation of adherence to different aspects of hemodialysis and medications.

Mellon et al. (2013) designed a study to assess the predictive value of demographic and psychological variables in non-adherence in hemodialysis patients. This study used a cross-sectional design with 50 hemodialysis patients. For this study adherence to fluid and dietary restrictions was measured using potassium, phosphorus, and inter-dialytic weight gain (IDWG). The study took place in three hemodialysis units in Ireland. To be considered for inclusion in this study the participants had to be willing to participate; established on hemodialysis treatment (≥90 days after first ever hemodialysis treatment); no severe cognitive disorder; no hearing impairment; English as the first language; 18 years of age or older. Exclusion criteria were if deemed acutely unwell by the medical team at the time of the study or if they had a diagnosis of dementia. The researchers collected data using questionnaires: demographic and clinical information, Hospital Anxiety and Depression Scale (HADS), Short Form 12-Item Survey (SF-12), Renal Adherence Attitudes Questionnaire (RAAQ), Renal Adherence Behavior Questionnaire (RABQ), and biochemical measures for potassium, phosphorus, and inter-dialytic weight gain (IDWG). The results revealed 62% of the participants were nonadherent with at least one aspect of the treatment regimen. Younger patients displayed poorer adherence to fluid restrictions and older patients demonstrated higher levels of adherence to fluid restrictions. The number of tools and questions could be considered limitations.

Walsh and Lehane (2011) developed a study determine adherence levels with dietary restrictions in Irish hemodialysis patients and to explore the relationships between adherence with dietary sodium restrictions and health beliefs in relation to following these restrictions in this group. This study used a quantitative, descriptive, correlational

design with a convenience sample of 79 patients. The study took place in the dialysis units of a large hospital in Ireland. To be considered for inclusion in this study the participants had to be 18 years of age or older, receiving hemodialysis for a minimum of three months, and have an adequate understanding of written and spoken English. Exclusion criteria were acute renal failure patients and non-Irish patients. The researchers collected data using three questionnaires: a demographic questionnaire which included age, gender, educational level, length of time on dialysis and nationality; the Renal Adherence Questionnaire (RAQ) which measured adherence to dietary restrictions; and the Beliefs about Dietary Compliance Scale (BDCS) which measured patients' beliefs regarding following the sodium-restricted diet. The results revealed that participants in this study had an accurate perception of the benefits associated with following dietary sodium restrictions but the participants also reported perceiving a moderate number of barriers (Walsh & Lehane, 2011). The results also revealed that increased 'perceived benefits' and reduced 'perceived barriers' were associated with greater levels of adherence (Walsh & Lehane, 2011). The most cited perceived barriers were 'following a low-salt diet is hard to do when I go out to eat' and 'food does not taste good on a low salt diet' A specific limitation of this study is that the researchers limited participants to only Irish patients.

Weisbord et al. (2014) designed a study to determine the associations between depressive symptoms and pain with dialysis adherence, health resource utilization, and mortality in patients receiving chronic hemodialysis. The study used a longitudinal design from 2009 to 2011 and took place in outpatient hemodialysis units in Western Pennsylvania. The sample included 286 participants. To be considered for inclusion in

this study the participants had to be cognitively intact and a patient at one of nine outpatient hemodialysis units in Western Pennsylvania. The researchers collected data using three questionnaires: a demographic questionnaire which included age, race, sex, income, educational status, dialysis vintage, form of vascular access, and burden of comorbid illness; the Patient Health Questionnaire-9 (PHQ-9) which assessed depressive symptoms of patients; and the Short-Form McGill Pain Questionnaire (SF-MPQ) which assessed patients' pain. The researchers assessed the patients' depressive symptoms and pain at the beginning of the study and then on a monthly basis during the study. The results revealed that in patients on chronic hemodialysis, depressive symptoms and pain are independently associated with dialysis nonadherence and health resource utilization, whereas depressive symptoms are also independently associated with mortality.

The researchers declared several limitations of this study: the patients were participants in a clinical trial of symptom management interventions, which may have affected their depressive symptoms, pain, and clinical outcomes. This study was conducted in a single geographic area, which may limit generalizability. The researchers used the PHQ-9 to assess depressive symptoms, which is not considered the "gold standard" tool for the diagnosis of major depression. Additionally, observational studies cannot establish causal associations and the researchers were unable to determine potential mechanisms linking depressive symptoms and pain with adverse outcomes. The longitudinal analyses presented simplify the potential associations between symptoms and outcomes. The researchers' assessment of ED visits relied on patient interviews and was potentially subject to recall bias (Weisbord et al., 2014)

Karavetian and Ghaddar (2013) developed a study to investigate the effect of self-management dietary counselling (SMDC) on adherence to dietary management of hyperphosphatemia among hemodialysis (HD) patients. The study used a randomized control trial with a sample of 87 patients. The study took place in Sidon, Lebanon. Group A received SMDC, Group B received educational games only and Group C did not receive any research intervention. To be considered for inclusion in this study the participants had to be stable on HD and had been on HD for at least three months,18 years of age or older, of Lebanese origin, and have full cognitive, psychiatric and physical capability for self-care and communication. The patients' demographic data and medical histories were collected from their medical records. A three month average of biochemical markers was collected prior to the study and then monthly during the study. The parameters included serum calcium, serum phosphorus (P), calcium and phosphorus product, parathyroid hormone, serum albumin, and calculated urea reduction ratio (URR). A patient knowledge (PK) questionnaire was used to assess patients' knowledge of kidney disease, renal diet, phosphate binders and vitamin D therapy. A patient dietary non-adherence (PDnA) to phosphate restricted diet questionnaire was also used to assess patients' dietary and phosphate binder intake. All three groups were assessed pre and post study for comparison of data. The results revealed a significant improvement in serum P levels (p=0.01) and PK scores (p=0.02) only in Group A. A significant improvement was observed in serum Ca and P product in both groups A (p=0.006) and B (p=0.01), but not in Group C. A significant improvement was noted in the overall PDnA score within Group A (p=0.01), but not in Group C. Participants in Group B showed a significant decrease in only one aspect of the PDnA questionnaire: intake of high P sweet items

(p=0.01). The researchers declared one limitation which was the study used a convenience sample of patients recruited from one dialysis center in Lebanon which may not represent the overall Lebanese HD population.

Wells (2011) designed a study to examine the relationship between hemodialysis knowledge and perceived medical adherence to prescribed treatment in African Americans. The study used a three group quasi-experimental design with a convenience sample of 85 African Americans. The study took place in Louisiana. To be considered for inclusion in this study the participants had to be African American, at least 18 years of age, on HD for at least one year, diagnosed with ESRD, able to speak, write, read, and understand English, oriented to person, place, and time, able to read and sign an informed consent, and able to successfully complete all research instruments and surveys. Exclusion criteria included patients with psychological disorders, cognitive disorders, or physical limitations in self-care and those individuals of any race other than African American. Group 1 received a pre-test, an educational intervention, a handout of content taught, and a post-test. Group 2 received a pre-test, no educational intervention, a handout of content taught, and a post-test. Group 3 received a pre-test and post-test only. The researchers collected data using three tools: a demographic questionnaire, The Life Options Hemodialysis Knowledge Test and the Medical Outcomes Study (MOS) General Measures of Patient Adherence. The results revealed there was a significant increase in HD knowledge after the education intervention, but no significant increase in perceived medical adherence. The author declared three limitations of the study: a lack of generalizability due to lack of random sampling; difficulty in understanding terminology on the research instruments; and interference of extraneous variables (interruptions by

others, visual distractions, temperature of room, noise level, and fatigue of the participants and individuals with co-morbid conditions) due to study conduction in the natural setting for HD (Wells, 2011).

Khalil, Frazier, Lennie, and Sawaya (2011) developed a study to examine the relationship between depressive symptoms and fluid and dietary adherence in patients with ESRD receiving hemodialysis. The study used a descriptive, cross-sectional design with a convenience sample of 100 patients. The study took place in seven hemodialysis units in Kentucky. To be considered for inclusion in this study the participants had to be older than 21 years of age, able to read and write English, free of major psychiatric disorders or cerebrovascular disease that affected cognitive ability, and receiving hemodialysis for at least three months. Exclusion criteria were the presence of a coexisting terminal illness, prescribed antidepressant medication at time of recruitment, history of missing more than one hemodialysis session in the previous two weeks or shortening a dialysis session by more than 10 minutes during the previous two weeks in the absence of a medically related reason, severe metabolic acidosis with serum bicarbonate level of greater than or equal to 12 mEq/l within the previous two weeks, and a mean urea reduction ratio (URR) less than 65% (Khalil et al., 2011). The researchers collected data using demographic and clinical information, the Dialysis Diet and Fluid Questionnaire (DDFQ), the Beck Depression Inventory-II (BDI-II), the Brief Symptom Inventory-Depression Subscale (BSI), and the Perceived Social Support Scale (PSSS). The results revealed for every one year increase in age the likelihood of dietary adherence increased by 5%. Neither education level, residual renal function, number of comorbidities, years of dialysis, or perceived social support was a statistically significant

predictor of fluid or dietary non adherence. Depressive symptoms were also an independent predictor of self-reported fluid and dietary non adherence.

Cicolini et al. (2012) designed a study to determine the influence of a family carer (FC) on hemodialysis patients' adherence. The researchers defined family carer as a person providing a wide variety of services to care recipients, such as daily household tasks, patients' diet, liquid intake and therapeutic plan adherence (Cicolini et al., 2012). The study used a case-control method. The study took place in Italy with 72 participants. To be considered for inclusion in this study the participants had to have a urine output of less than 200ml per day and receiving HD three times per week for more than three months. Exclusion criteria were patients not able to give a valid consent (psychiatric disorders, severe physical impairment) or with a urine output of more than 200 mL per day. The results revealed that the presence of a FC improves the HD patients' adherence to potassium and phosphorus restrictions and interdialytic weight gain. The researcher declared two limitations of the study: a patient's residual urine volume/ residual kidney function. Patients who still produce large volumes of urine must adhere to less strict fluid restrictions than patients who are anuric. A second limitation is the short period of time covered by this study (four months) and the sample size.

CHAPTER III

Methodology

The design of this research study consisted of a retrospective chart review in two freestanding hemodialysis clinics in a midsized city in the southeastern United States applying Roy's Adaptation Model as the theoretical framework.

Setting

This study was conducted at two freestanding outpatient hemodialysis clinics in a midsized city in the southeastern United States. The freestanding outpatient hemodialysis clinics are part of a well-established corporation. The corporation provides outpatient hemodialysis services, chronic kidney disease (CKD) services, hospital hemodialysis services, home hemodialysis services, home peritoneal dialysis services, as well as donor services in hundreds of facilities across more than 25 states in the United States. The company employs over 5,000 people and provides services to over 15,000 patients. The two clinics, in which the data collection took place, serve approximately 80 patients combined and provide only outpatient hemodialysis services.

Sample

The sample for this research study consisted of a convenience sample of patient's charts in two freestanding outpatient hemodialysis clinics (approximately 80 patients). A retrospective chart review including four weeks of information was used for data collection. For inclusion in this study, patients must be receiving hemodialysis in the clinics for six weeks and be 18 years of age or older. The following demographic information was collected for this study: age, race, cause of ESRD, gender, marital status, and hemodialysis vintage (how long a patient has been on hemodialysis).

Protection of Human Subjects

The study is retrospective and involves the use of existing records housed in the sample populations' dialysis clinic medical record. The chart review included four weeks of data from a combination of paper charts, electronic medical records, and reports. The information recorded by the researcher did not identify any patients. No linking lists were maintained by the researcher. No protected health information (name, address, SS#, etc.) was collected. The research involved minimal risk to subjects. The research protocol was submitted to the study site and the sponsoring university IRB committees for review. The study began upon approval of both entities (Appendix A and B). Chart audit tools and research data was maintained by the researcher in a password protected computer in a locked office. Upon completion of the study, data was submitted to the University for secure storage for a minimum of three years.

Instruments

The following information was collected for this study: treatment attendance (three days per week), including shortening treatment, adherence to fluid restriction and potassium and phosphorus values. Adherence to fluid restriction was defined as a patient is gaining three kilograms (3kgs) or less between treatments. The following demographic information was also collected for this study: age, race, cause of ESRD, gender, marital status, and hemodialysis vintage (how long a patient has been on hemodialysis). The exceptions to missed treatment is if the patient is hospitalized or if the patient makes up a missed treatment on a different day. The exception to shortened treatment is if it was deemed medically necessary by HD staff. Data was collected using a chart audit tool

developed by the researcher based on best evidence. The tool was not tested for validity or reliability.

Procedure

A chart review included four weeks of data from a combination of paper charts, electronic medical records, and reports. A chart audit tool developed in a spreadsheet format was used to collect the data (Appendix C). The study was conducted by the researcher and no other individuals.

Research Definitions

- Treatment attendance- attending treatment three days per week and not shortening the treatment.

- Adherence to fluid restriction- gaining three kilograms or less between treatments.

- Demographic information-age, race, cause of ESRD, gender, marital status, and hemodialysis vintage (how long a patient has been on hemodialysis). Lab values for potassium and phosphorus were collected and evaluated to determine if the results were within normal ranges. For this facility- normal potassium is 3.5 -5.5 mg/dl and normal phosphorus is 2.6-5.5 mg/dl.

Data Analysis

Data was analyzed using the Statistical Package for the Social Sciences (SPSS) Windows version 24. Data was coded during analysis and analyzed using Logistic Regression.

CHAPTER IV

Results

Data was collected between May 1st and May 31st, 2017. Of the 80 total patients

from both clinics combined, 75 met the inclusion criteria. Data collection results were

coded and entered in the Statistical Package for the Social Sciences (SPSS) Windows

version 24 for analysis.

Demographic Information

The demographic information collected for this study were age, race, cause of

ESRD, gender, marital status, and hemodialysis vintage (how long a patient has been on

hemodialysis).

The study participants ranged from 27 to 89 years of age with the largest age

group being 62-72 at 33.3% (n=25). A large majority of the sample was of the African

American race at 60% (n=45) compared to Caucasian participants at 32% (n=24).

Diabetes was documented as the cause of ESRD for 52% (n=39) of the sample while

hypertension was documented as the cause of ESRD for 24% (n=18). Other causes of

ESRD which included AIDS nephropathy, glomerulonephritis, glomerulosclerosis,

chronic interstitial nephritis, and unknown etiology represented 22.7% (n=17) of the

sample. The majority of the sample was female (n=43) compared to males (n=32). The

marital status of married was documented for 37.3% (n=28) of the study sample. The

majority of the study sample had been receiving hemodialysis (HD vintage) for one to

four years at 41.3% (n=31) followed by five to eight years at 26.7% (n=20). There were

five patients who had been receiving hemodialysis for greater than 12 years. Tables 1-6

represent the frequencies and percentages for the demographic characteristics of the sample.

Table 1

Frequencies and Percentages of the Age Variable

Age	Frequency	Percent
18-28	1	1.3
29-39	2	2.7
40-50	4	5.3
51-61	22	29.3
62-72	25	33.3
73-83	16	21.3
Over 83	5	6.7

Table 2

Frequencies and Percentages of the Race Variable

Race	Frequency	Percent
Caucasian	24	32.0
African American	45	60.0
Hispanic	1	1.3
Other	2	2.7
Unknown	3	4.0

Table 3

Frequencies and Percentages of the Cause of ESRD Variable

Cause of ESRD	Frequency	Percent
Hypertension	18	24.0
Diabetes	39	52.0
Polycystic Kidney Disease	1	1.3
Other	17	22.7

Table 4

Frequencies and Percentages of the Gender Variable

Gender	Frequency	Percent
Male	32	42.7
Female	43	57.3

Table 5

Frequencies and Percentages of the Marital Status Variable

Marital Status	Frequency	Percent
Married	28	37.3
Single	17	22.7
Divorced/widowed	24	32.0
Unknown	6	8.0

Table 6

Frequencies and Percentages of the HD Vintage Variable

HD Vintage	Frequency	Percent
Less than 1yr	12	16.0
1-4yrs	31	41.3
5-8yrs	20	26.7
9-12yrs	7	9.3
Greater than 12yrs	5	6.7

Adherence Results

Of the total study sample 76% (n=57) attended treatment three days per week, while 24% (n=18) attended treatment less than three days per week. Table 7 represents the frequencies and percentages of the treatment attendance results. Of the total study sample 38.7% (n=29) shortened their treatment, while 50.7% (n=38) did not shorten their treatment. It was deemed medically necessary for 10.7% (n=8) of the study sample to shorten their treatment. Table 8 represents the frequencies and percentages of the shortened treatment results.

Table 7

Frequencies and Percentages of Treatment Attendance

Treatment Attendance	Frequency	Percent
3 days per week	57	76.0
less than 3 days per week	18	24.0

Table 8

Frequencies and Percentages of Shortened Treatment

Shortened treatment	Frequency	Percent
Yes	29	38.7
No	38	50.7
Medically Necessary	8	10.7

Of the total study sample 36% (n=27) gained three kilograms or less between treatments, while 64% (n=48) gained more than gained three kilograms between treatments. Table 9 represents the frequencies and percentages of the adherence to fluid restriction results.

Table 9

Frequencies and Percentages of Adherence to Fluid Restriction

Adherence to fluid restriction	Frequency	Percent
gained 3kgs or less between treatments	27	36.0
gained more than 3kgs between treatments	48	64.0

Of the total study sample, 15 were adherent in all three measures of adherence (treatment attendance, did not shorten treatment/medically necessary, and fluid restriction). Of the 15 that were adherent in all three measures of adherence, six of them were married. Out of the total 75 participants, 41 attended treatment and did not shorten their treatment or it was deemed medically necessary. Of the 41 that attended treatment and did not shorten their treatment or it was deemed medically necessary, 17 were married. Only 10 participants were adherent in all three measures of adherence and had

their potassium and phosphorus levels within therapeutic range. Of the 10, only four were married.

Potassium and Phosphorus Results

Lab values for potassium and phosphorus were collected and evaluated to determine if the results were within normal ranges. The potassium level was within normal range for 94.7% (n=71) of the sample, while 5.3% (n=4) had a potassium level greater than 5.5 mg/dl. Table 10 represents the frequencies and percentages of the potassium results. The phosphorus level was within normal range for 56% (n=42) of the sample, while 42.7% (n=32) had a phosphorus level greater than 5.5 mg/dl. And 1.3% (n=1) of the sample had a phosphorus level less than 2.6 mg/dl. Table 11 represents the frequencies and percentages of the phosphorus results.

Table 10

Frequencies and Percentages of Potassium Level

Potassium	Frequency	Percent
3.5 -5.5 mg/dl (therapeutic range)	71	94.7
greater than 5.5	4	5.3

Table 11

Frequencies and Percentages of Phosphorus Level

Phosphorus	Frequency	Percent
2.6-5.5 mg/dl (therapeutic range)	42	56.0
less than 2.6	1	1.3
greater than 5.5	32	42.7

Major Findings

The data was entered into Statistical Package for the Social Sciences (SPSS)

Windows version 24 using Logistic Regression to analyze the results. Primary analysis of

the data revealed the martial status variable was significantly associated with treatment

attendance with a p-value of 0.047. Table 12 represents regression of treatment

attendance and marital status. With further analysis, when treatment attendance was

regressed on the marital status levels, the level of "married" was significantly associated

with treatment attendance with a p-value of 0.038. Table 13 represents treatment

attendance regressed on marital status levels. Table 14 represents regression of adherence

to fluid restriction. No statistically significant correlations with adherence to fluid

restriction were found.

Table 12

Regression of Treatment Attendance Marital Status

Variable	B	S.E.	Wald	df	Sig.	Exp(B)
Age	-.214	.248	.740	1	.390	.808
Race	-.075	.325	.053	1	.818	.928
Cause of ESRD	.305	.275	1.237	1	.266	1.357
Gender	-.442	.613	.520	1	.471	.643
Marital Status	.610	.307	3.943	1	.047*	1.841
HD Vintage	-.077	.269	.083	1	.774	.926
Constant	-1.191	2.036	.342	1	.559	.304

Note * indicates level of significance at p< .05

34

Table 13

Treatment Attendance Regressed on Marital Status Levels

Marital Status	B	S.E.	Wald	df	Sig.	Exp(B)
(Married) Marital Status 1	-2.120	1.020	4.323	1	.038*	.120
(Single) Marital Status 2	-.606	.961	.398	1	.528	.545
(Divorced) Marital Status 3	-1.099	.943	1.358	1	.244	.333

Note * indicates level of significance at p< .05

Table 14

Regression of Adherence to Fluid Restriction

Variable	B	S.E.	Wald	df	Sig.	Exp(B)
Age	-.392	.246	2.527	1	.112	.676
Race	-.308	.339	.825	1	.364	.735
Cause of ESRD	-.258	.262	.966	1	.326	.773
Gender	-.280	.545	.263	1	.608	.756
(Married) Marital Status1	-1.511	1.326	1.298	1	.255	.221
(Single) Marital Status2	-2.071	1.351	2.348	1	.125	.126
(Divorced) Marital Status3	-2.130	1.320	2.604	1	.107	.119
HD Vintage	.440	.271	2.637	1	.104	1.552

Summary

Over half of the study sample was African American (60%), 57.3% of the sample was female, and the largest age range was 62-72 years old at 33.3%. Diabetes was the documented cause of ESRD for 52% of the sample and 41.3% of the sample had been receiving hemodialysis for one to four years. A large majority of the study sample was married (37.3%). The potassium was in therapeutic range for 94.7% of the sample and phosphorus was in therapeutic range for 56% of the sample. Regarding treatment adherence 76% of the study sample was adherent to treatment attendance (three days per week), 50.7% did not shorten their treatment time, but 64% gained more than three kilograms between treatments.

CHAPTER V

Discussion

This study was conducted to determine which demographic factors were correlated with adherence to hemodialysis treatment regimen. This research study revealed many interesting findings regarding the current study sample, but being married demonstrated a statistically significant correlation with treatment attendance (p= .038, p was significant at the .05 level). For this study treatment attendance was defined as attending treatment three days per week.

Implication of Findings

The demographic factor of being married having a correlation with adherence to hemodialysis treatment regimen may indicate the spouse is a support system or a care partner. The patient's spouse may encourage the patient to attend hemodialysis treatment as recommended and hold them accountable. This finding is partially consistent with research conducted by Theofilou (2013) regarding marital status as a significant factor in adherence. Theofilou (2013) found married patients showed significantly higher scores of medication adherence than patients that were single, widowed, or divorced. The finding of this study is also partially consistent with research conducted by Cicolini et al. (2012) whom designed a study to determine the influence of a family carer (FC) on hemodialysis patients' adherence. The term family carer, which could be interpreted as a spouse, was defined by the researchers as a person providing a wide variety of services to care recipients, such as daily household tasks, patients' diet, liquid intake and therapeutic plan adherence (Cicolini et al., 2012). The results of the study conducted by Cicolini et al.

(2012) revealed that the presence of a FC improves the HD patients' adherence to potassium and phosphorus restrictions and interdialytic weight gain.

Unfortunately, none of the other demographic factors (age, race, cause of ESRD, gender, or HD vintage) demonstrated a correlation with adherence to hemodialysis treatment regimen. It was hypothesized that older age, the female gender, and a longer HD vintage would have shown a significant correlation with one of the three measures of adherence for this study (treatment attendance, shortened treatment, and adherence to fluid restriction). Ossareh et al. (2014) found that older age was associated with adherence and the male sex was associated with nonadherence. Mellon et al. (2013) found that older patients demonstrated higher levels of adherence to fluid restrictions. Khalil et al. (2011) discovered that for every one year increase in age the likelihood of dietary adherence increased by 5%. Regarding adherence results, it was encouraging to discover that 76% of the sample attended treatment three days per week and 50.7% did not shorten their treatment. And although potassium and phosphorus were not used as measures of adherence, it was outstanding to learn potassium was in therapeutic range for 94.7% of the sample and phosphorus was in therapeutic range for 56% of the sample since these lab values can have a significant impact on patient health if they are out of therapeutic range.

Application to Theoretical Framework

There are many different factors that influence a patient's ability to adhere to their recommended treatment regimen. The four adaptive modes of Roy's Adaption Model are physiologic-physical mode, self-concept-group identity mode, role function mode, and interdependence mode (Gonzalo, 2011). The physiologic-physical mode relates to the

need for balance to be maintained regarding fluid, electrolytes, and acid-base balance (Minnesota State University Mankato, n.d). For this study, maintaining fluid, electrolytes, and acid-base balance can be interpreted to mean hemodialysis treatment attendance. The self-concept-group identity mode relates to interpersonal relationships (MSUM, n.d). In terms of the current study interpersonal relationships could be interpreted to mean the interaction between husband and wife. The role function mode is pertaining to the roles a person has (MSUM, n.d). For this study, the roles a person has could refer to being a wife or husband. The interdependence mode relates to interaction with significant others (MSUM, n.d). Pertaining to this study interaction with significant others may signify the relationship between husband and wife.

Implications for Nursing

The results of this study can be used by nephrology nurses to develop a new process for assisting patients to adapt to living with end stage renal disease. By recognizing that patients that lack spousal support and encouragement may be more at risk of treatment non-adherence, nurses can proactively support these patients through education and building a therapeutic relationship. The entire interdisciplinary care team, including social workers, could be beneficial to single patients.

Limitations

This study had two major limitations: the small sample size of two outpatient hemodialysis clinics (75 patients) and a retrospective chart review including only four weeks of information. Consequently, the findings of this study were hard to generalize for all outpatient hemodialysis patients.

Recommendations

Due to the small sample size of two outpatient hemodialysis clinics and a retrospective chart review including only four weeks of information, the researcher recommends future studies use a larger sample size. In addition, the researcher recommends future studies utilize a longer time frame for retrospective chart review possibly six months to one year of data to obtain results that are easier to generalize.

Conclusion

The findings of this research study revealed a statistically significant correlation between being married and treatment attendance. The literature review provided evidence from two previous studies, Theofilou (2013) and Cicolini et al. (2012), found being married/family carer had a significant impact on patient adherence.

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Appendix A

University Institutional Review Board Approval

Dear Ms. Ross and Dr. Hamrick,

Your research study titled "Demographic Factors that Correlate with Adherence to Hemodialysis Treatment Regimen" has been approved by the Gardner-Webb University Hunt School of Nursing's IRB for the period indicated. It has been determined that this study falls into the review category of Exempt.

Approval Date: 4/20/17
Expiration Date: 4/20/18

Investigator's Responsibilities

Federal regulations require that all research be reviewed at least annually. It is the Principal Investigator's responsibility to submit for renewal and to obtain approval before the expiration date. You may not continue any research activity beyond the expiration date without IRB approval. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.

You are required to obtain IRB approval for any changes to any aspect of this study before they can be implemented. Should any adverse event or unanticipated problem involving risks to the participants or others occur, the events must be reported immediately to the Hunt School of Nursing IRB representative.

During your study, you must retain all instruments/forms/surveys and data. Prior to the presentation of your data within the Hunt School of Nursing Research Day, you must submit all instruments/forms/surveys along with your data to the IRB representative. Failure to submit this information prior to the presentation will result in an inability to present your findings and will impact your graduation date. Prior to graduation, it is the responsibility of the student and the advisor/chair to ensure that this IRB is closed using the appropriate form.

Please contact me with any questions.

Best wishes on your research.

Sincerely,

Cindy Miller, PhD, RN
IRB Representative
Hunt School of Nursing

Appendix B

Institution Approval to Conduct Research

DCi

Dialysis Clinic, Inc.
A Non-Profit Corporation

Office Of Clinical Research
Administrative Review Office

May 10, 2017

Brittany Ross, RN
121 Lake Robinson Point
Greer, SC 29651

Re: 2017.06   (*Please reference this number in all correspondence*) Demographic Factors that Correlate with Adherence to the Hemodialysis Treatment Regimen

Clinic(s):   Union 094   Landrum 177

Update Due: 4/20/2018 -   *Please note: the DCI ARO approval will expire the same date as your IRB approval.*

Dear Ms. Ross:

The DCI Administrative Review Office ("ARO") is pleased to inform you that the above referenced research project has been reviewed and approved. Please note the ARO Policy requires that each research project approved by the ARO must be reviewed at least on an annual basis.

To meet the requirements of the ARO the following conditions must be met:

- The Gardner-Webb University is the IRB of record for this study, and since the ARO is authorized to approve only projects that have been approved by an IRB, if IRB approval is ever withdrawn the research project must immediately cease.

- A copy of all publications that arise from this research study must be submitted to the ARO.

- After the IRB of record has completed its continuing review of the research project, please submit a copy of the updated IRB approval, along with a copy of the completed Continuing Review Report. The research project may not continue until it has been approved by both the IRB of record and the ARO.

- Modifications to the research project must be reviewed by the IRB of record prior to the initiation of those changes. Please forward copies of documents that are sent to the IRB of record for this project along with the corresponding IRB approval letters to the ARO. This information may include, but is not limited to:

  o Significant changes to the research study's consent and/or protocol (i.e. change in study personnel, increase in study duration, change in study drug dosage, additional study procedures, any change which affects the level of risk, etc)
  o Serious adverse events reports or unanticipated problems
  o Safety reports
  o Periodic updates
  o Protocol deviations and/or violations
  o Participant complaints

1633 Church Street, Nashville, TN 37203
Phone 615/327-3061, Fax 615/329-6705

DIALYSIS CLINIC, INC.

- o IRB acknowledgment of closure

- The ARO has the authority to suspend or terminate approval of research that is not being conducted in accordance with ARO requirements or that has been associated with unexpected serious harm to subjects.

Should you have any questions or comments, please do not hesitate to contact the ARO office.

Sincerely,

Karen Majchrzak
DCI Director of Clinical Research

cc:
AnnMarie Roberts
Eric Lee
Lawrence McGee, MD
Muhammed Ebrahim, MD

Appendix C

Chart Audit Tool

Chart Audit Tool

Patient	Age	Race	Cause of ESRD	Gender	Marital Status	HD Vintage	Treatment Attendance	Shortened Treatment	Potassium	Phosphorus
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2										
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