Motivational Approach to Improve Adherence to Phosphorus Management in Adults Undergoing Outpatient Hemodialysis

By

Ian A. Villanueva

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Abstract

Patients with chronic renal disease commonly have elevated serum phosphorus levels, which is associated with increased morbidity and mortality due to its effects on the cardiovascular and musculoskeletal system.This is known as hyperphosphatemia, which occurs with renal disease due to the kidney's decreased ability to excrete ingested phosphorus. The effects are significant due to cardiovascular disease being one of the leading causes of death in end-stage renal disease (ESRD), thus making phosphorus management an important goal. The objective of this project is to ascertain the effectiveness of motivational approach to improve adherence of adults undergoing outpatient hemodialysis to phosphorus management.

Adults over 18 years old with a 3-month phosphorus average higher than 5.5 mg/dl were included, while those with normal results in that time span were excluded. A one month motivational and educational intervention was done for each individual participant. Quantitative study was done to determine the significance of changes from interventions. Outcomes were measured though serum phosphorus level, patient knowledge, and adherence to phosphorus management. Results were obtained from the dialysis clinic's electronic health record (EHR). Results were processed with T tests, which gained statistically insignificant results. This project, overall, improved the participants' motivation and understanding regarding phosphorus management.Long-term motivational interventions could improve phosphorus control.

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Chapter I: Introduction

Background, Significance, and Aims

Patients on hemodialysis in the outpatient setting face many hurdles as they have multiple comorbidities (Umeukeje, Merighi, Browne, Carlsson, Umanath, Lewis, Ikizler, Wallston, & Cavanaugh, 2015). This means they have to take multiple pills each day (called the pill burden) and adhere to a complex diet in addition to maintaining a strict fluid restriction. Added to such problems is trying to maintain a normal serum phosphorus level. A lot of patients in the outpatient hemodialysis setting struggle to maintain a normal serum phosphorus level, which results in increased risk of vascular calcification, cardiac hypertrophy, worsening secondary hyperparathyroidism and higher mortality (Jablonski &Chonchol, 2014). Even if staff educates patients on a daily basis, the patients still struggle to maintain proper phosphorus control due to the fact that having a diet that restricts phosphorus intake may also restrict protein intake. Most protein rich foods have moderate to high amounts of phosphorus (Kalantar-Zadeh, 2013). This is in addition to the fact that controlling phosphorus may also add to their pill burden, because they must take their phosphorus binding medications with food.

Maintaining normal blood levels of phosphorus has been linked to longer life and lower risks of having a cardiovascular event, organ damage/failure, joint/bone pain, among others (Jablonski &Chonchol, 2014). There is a need to explore other possible ways to control the phosphorus, one such a method is a motivational approach to help patients cope with phosphorus control.

Patients with end-stage renal disease (ESRD) develop hyperphosphatemia due to their kidneys' inability to completely excrete excess phosphorus ingested from their diet (Milazi, Bonner, & Douglas, 2017). The management of serum phosphorus levels for adult outpatient hemodialysis patients continues to be a problem for patients and a hurdle for healthcare practitioners who are trying to improve patient outcomes. This leads to hyperphosphatemia, which if left unmanaged, will significantly increase the morbidity and mortality of these patients. Hyperphosphatemia also leads to lower serum calcium levels; impairs the activation of vitamin D, causing malabsorption of calcium from the gastrointestinal tract (GIT); and poor utilization of both these minerals leads to mineral and bone disease. When phosphorus levels increase beyond 1.78 mmol/l or 5.5 mg/dl, the combination of calcium and phosphate results in the formation of crystals that can deposit into soft tissues and blood vessels and damage them. This might also lead to something much worse, which is when calcification reaches the arterial media. This problem is referred to as *calciphyilaxis*, which is a heavy contributor to the morbidity and mortality of ESRD patients (Milazi, Bonner, & Douglas, 2017). Hemodialysis alone cannot correct phosphorus levels as it only removes less than 50% of the daily ingested phosphorus (Grossman &Porth, 2014).

The cornerstone in maintaining phosphorus homeostasis is restricting intake through diet and use of different medications that bind to and precipitate phosphorus in the bowel to prevent its absorption. These medications are called phosphorus binders (Kalantar-Zadeh, 2013). Renal diet is difficult to follow. Even with proper dietary instructions and extensive educational programs, patients continue to struggle finding the right food as most low phosphorus foods are also poor sources of protein, which is essential for survival in patients with ESRD. Furthermore, when phosphorus levels rise, patients are treated with phosphorus binders that should be taken with every meal and snack, multiple times per day, which invariablyincreases pill burden.

Despite constant education by dieticians, nurses, and nephrologists, patients with ESRD continue to struggle with phosphorus management. Occasionally, some patients interpret such education and reminders as constant, unnecessary nagging. Such background of information leads to the motivational approach, which is focused on individual patient to identify their burden in order to come up with a plan to motivate them to adhere/follow their phosphorus control regimen (Umeukeje et al., 2015).

The goal of this project is to improve patients' serum phosphorus by creating a tool that will increase their motivation to improve phosphorus control. Such a tool would help these patients understand and accept the importance of proper diet and medication by identifying problem areas that could be incorrect health belief and how to improve on them. The main beneficiary from this project will be the patients themselves, in addition to the treating physician, the dialysis unit, and dialysis staff.

Considering the important role dialysis staff, especially nurses, play in the care of patients with ESRD on hemodialysis, improving patient outcomesis in congruence with the mission statement of Washington Universityof advancing human health through best care, inventive research, and education of future leaders that reinforces diversity, inclusion, critical thinking and creativity (Washington University School of Medicine [WUSM], 2018). This project also abides by their visions of promoting excellence, outstandingly creative research, and the application of research advances for better care. The WUSM’s hemodialysis clinic, like most dialysis clinics,is ready for a change in approach for quite some time. Almost half of the patients struggle to control their phosphorus level due to multiple factors such as poor socioeconomic status, poor health literacy or reduced access to appropriate and healthy diet. Furthermore, this might also be based on their own beliefs and perception of hyperphosphatemia and their self-perceived vulnerability to it.

This project aimed to improve the phosphorus levels of adults undergoing outpatient hemodialysis after one month of intervention. Otherwise, it would at least help them realize and verbalize obstacles and opportunities to better manage their phosphorus. Having them learn what they can and should do will benefit them long-term.

This project was cost effective, since the work was done through one on one interview while patients are undergoing their hemodialysis treatments, and the implementation would be also through verbal interaction. Moreover, the dialysis staff arekeen to help improve patient outcomes and are eager to participate.Evaluation of serum phosphorus will be through the electronic health record (EHR) system currently in use at the clinic.

Clinical Research Question (PICOT)

In adults undergoing outpatient hemodialysis (P), does educating and motivating them to adhere to their phosphorus management (I) compared to educating them only (C), result in improved serum phosphorus levels (O) after a period of one month (T)?

The dependent variable will be the patients' serum phosphorus levels, which will be subject to motivational approach for improvement. The motivational approach is aimed at identifying personal barriers, perceived susceptibility, and patient knowledge through interviewing to help strengthen their weak areas to improve their phosphorus control.

Chapter II: Review of Literature

Search Process

The databases used to collect data were Cumulative Index to Nursing and Allied Health (CINAHL), Cochrane Library, National Center for Biotechnology Information, and Google. The Bradley University's library was also utilized to gain additional resources through one of the librarians, Megan Jaskowiak. Keywords used for searches were *motivational, hemodialysis, phosphorus control adherence, education, phosphorus levels, and self-motivation.* There were a total of 12 studies found that were significant for this project.However, studiesof motivational approach for better phosphorus management are rare.The decision on which studies to use for this project was based on their significance in solving motivational problems, or lack thereof, in their phosphorus management, and onhow they can help in creating a tool that improve serum phosphorus levels in ESRD patients through improved adherence. The articles and studies used/referenced were within the last 5 years or the latest version as much as possible and had significant relevance to this application. Most studies targeted improving potassium control, which is a common problem in dialysis, while other studies were theoretical approaches to develop a solid hypothesis.

Synthesis of Evidence

Comparing the Studies

Milazi, Bonner, and Douglas (2017) suggested that targeting the gaps between what patients know (educational) and their motivation to adhere to their phosphorus management was more effective than just focusing on one aspect. They screened studies, where relevant ones were chosen were examined by independent reviewers for risk of bias before being included through the use of a standardized tool from the Joanna Briggs Institute Meta-Analysis of Statistics Assessment and Review Instrument (JBI-MAStARI). They obtained their data from using the same tool mentioned, which included interventions, populations, study methods, and significance of outcomes to their review. They concluded that educational and behavioral approaches improved patient adherence to phosphate control from their systematic review.

The studies done by Brogdon (2013); Cupiste, Ferretti, D'Alessandro, Petrone, Di Giorgio, Meola, Panichi, Conti, Lippi, Caprioli, and Capitanini (2012); and D'Alessandro, Piccoli, and Cupiste (2015) focused on either educational gap or hemodialysis patients' lack of motivation. Their studies were set to assess the effectiveness of self-care educational intervention in improving patient knowledge in dietary phosphorus management in hemodialysis patients. One of their final conclusions was the need for further research in determining factors that adds to patients' non-adherence to phosphorus control regimen.

Umeukeje et al. (2015) also similarly headed along the same route of focusing on a motivational approach like Milazi, Bonner, and Douglas' (2017) work. Umeukeje et al. (2015) studied 100 dialysis patients, determining the association of self-motivation to phosphorus control adherence with phosphate binders. McCarley (2013) also delve into the motivational route through motivational interviewing by promoting self-management and identifying behavior that leads to non-adherence to phosphate binders.Educating patients to improve serum phosphorus control (Brogdon, 2013) to prevent hyperphosphatemia, which lead to complications such as calciphylaxis, increased risk for stroke, soft tissue damage, and eventually death (Jablonski &Chonchol 2014).

Studies of Fouque, Home, Cozzolino, and Kalantar-Zadeh (2014) together with a separate study done by Kalantar-Zadeh (2013) discussed the importance of educating patients on hemodialysis about their phosphorus intake in order to balance the need for phosphorus control and maintain good protein intake as high protein foods, such as meat, are also high in phosphorus. Educating patients to balance nutritional needs should be part of the approach, because protein restriction can be very detrimental in such patients. This was also covered by the study of Cupiste et al. (2012) whofocused on balancing nutrition.They also suggested that having group classes and meetings for hemodialysis patients conducted on a scheduled basis can be helpful. These studies about educating patients also encourages the patients to participate more in their own care and to improve their knowledge about how to control phosphorus through good diet and binders. In conclusion, these studies suggest that there is a gap and room for improvement when it comes to serum phosphorus control in adult patients undergoing hemodialysis. This is especially important in cases of patients who develop renal disease from non-adherence to hypertension and diabetes management (Jablonski &Chonchol 2014).

Contrasting the Studies

Milazi, Bonner, and Douglas (2017)examined both educational and motivational approach to improve serum phosphorus levels of their subjects on hemodialysis. This study was the most recent (published in 2017)and tried to address the three methods of serum phosphorus control which are (1) dietary phosphate restrictions,(2) phosphate binder adherence, (3) and compliance with hemodialysis prescription.*The study stressed that the approach is only effective if it is reinforced by continued education.*They found that current evidence was limitedregarding knowledge of patients, their adherence, and belief in treatment effectiveness and their significance in managing serum phosphorus level.Most patients do only one out of the three facets of phosphorus.

The study by Chiu, Teitelbaum, Misra, de Leon, Adzize, and Mehrotra (2009) is unique as they focused on pill burden felt by patients with ESRD who aretaking phosphate binders. High pill count is linked to poor adherence in general, as well as lower quality of life.They found that the*daily pill burden of patients with ESRDis highest among patients with chronic diseases* (i.e. heart failure, lung disease, cancer, etc.)*and phosphate binders contribute to around half of the daily pill burden of renal patients.* Therefore, it is not surprising that they concluded that increasing the dosage of phosphate binders (pill burden) is effective due to worsened adherence.

A certainly unique take was the study done by Jablonski and Chonchol (2014) due to their focus on the burden brought by cardiovascular disease (CVD) which is exacerbatedby worsening chronic kidney disease (CKD).Jablonski and Chonchol’s (2014) study gave insight and foresight when planning an approach in terms of areas that may need to be covered when education and motivating patients who struggle in phosphorus control.

While all the aforementioned studies had the same goal of improving phosphorus control, their approaches were different. Some focused on improving patient knowledge through education, such as with the studies of Brogdon (2013);Cupiste et al. (2012);D'Alessandro, Piccoli, and Cupisti (2015); Fouque et al. (2014); and Kalantar-Zadeh (2013). However, other studies such as McCarley (2013) and Umeukeje et al. (2015) studiedwhether motivational interviewing and improving self-drive can improve phosphorus control. The exception was the study by Milazi, Bonner, and Douglas (2017), which included all three aspects previously mentioned to implement a positive change in hemodialysis patients' serum phosphorus level.

Theoretical Framework

This project utilized the Health Beliefs Model (HBM), which was developed in the 1950's by Hochbaum, Rosenstock, and Kegels while working in the U.S. Public Health Services (University of Twente, 2017).The theory is based on the concept that a person will engage in activities relevant to health if that person (1) perceives a disease can be prevented, (2) understands that taking the suggested actions will prevent an ailment, and (3) if the person believes he/she can successfully implement the recommended actions. It was necessary for the success of this project to improve phosphorus levels of adult outpatient hemodialysis patients by identifying factors on what would motivate them to increase their adherence to treatment. The HBM helped in developing methods to help these patients identify personal barriers to adherence that staff nurses can use while working with them during their hemodialysis treatment. The HBM also encompasses identification of perceived susceptibility, severity, benefits, personal barriers, readiness for action, and a patient's confidence in his/her ability to take actions to manage phosphorus levels (University of Twente, 2017).

Organizational Assessment & Cost Effectiveness Analysis

The hemodialysis clinic is ready for a change in approach for quite some time.Almost half of the patients struggle to control their phosphorus level due to multiple factors such as poor socioeconomic status, poor health literacy or reduced access to appropriate and healthy diet. Furthermore, this might also be based on their own beliefs and perception of hyperphosphatemia and their self-perceived vulnerability to it. Subjects might find suggested changes and the interview process to be bothersome during their treatments if they want to sleep through instead.The trusting relationship already established with the subjects due to the DNP nurse being part of the staff will help facilitate the implementation of this scholarly project.

The dialysis staff is also keen to help patients to improve phosphorus control. Collaboration is a key part of this scholarly project. This is due to the project team being a diverse group of people coming from different fields of healthcare. The mentor being a nephrologist providing guidance, DNP student being a nurse, as well as having a dietician help with the selection of subjects, facilitate interventions and the evaluation their of results.

There will be no risk or unintended consequence for the subjects due to this project being noninvasive for being focused on motivation on improving their adherence to diet and medication regimen. This will be done through the identification of personal barriers, beliefs, and family structure to create an individualized plan of care. In addition, finding cost-effective ways of having better food options, exploring their beliefs, what motivates them, and perhaps have their families help them better control the subjects' phosphorus. This project offers many benefits from its success without body-altering risks. The results will benefit the organization, its patients/clients, and researches who might be interested in further exploring such an approach, not just for phosphorus control, but perhaps for other matters to improve patient outcomes.

This project will be cost effective, since by doing motivational activities, the time spentto educate patients will not be wasted.Improving patient knowledge and adherence will be cost-effective as it might also improve overall outcome.This will be beneficial for both patients and the dialysis clinic and can improve patients' quality of life, as it may reduce their disease burden and hospitalization. The evaluation of results will be through the assessment of monthlylaboratory results through the existing electronic health record (EHR). In short, all the necessary resources and tools are already present at the clinic.

Chapter III: Methodology

Needs Assessment

The purpose of this study is to determine the effectiveness of motivational approaches to help adult outpatient hemodialysis patients to improve phosphorus control. There is an obvious need to improve adherence to phosphorus control regimen based on the articles and experience as a dialysis nurse. Many patients in the outpatient hemodialysis setting struggle in maintaining a normal serum phosphorus level, which results in complications, increased morbidity, and increased mortality. Even if staff educates such patients on a daily basis, the patients will continue to struggles to maintain proper phosphorus control due to conflicting dietary requirements. Furthermore, using higher doses (more pills) of phosphorus binders is not usually effective as it adds to patients' pill burden.

Unmanaged phosphorus in this patient population leads to hyperphosphatemia and will significantly increase the morbidity and mortality of these patients (Milazi, Bonner, & Douglas, 2017). Hyperphosphatemia also leads to lower serum calcium levels; impairs the activation of vitamin D, causing malabsorption of calcium from the gastrointestinal tract (GIT); and poor utilization of both these minerals leads to mineral and bone disease. When phosphorus levels exceed1.78 mmol/l (5.5 mg/dl), the combination of calcium and phosphate results to the formation of crystals that can deposit into soft tissues and blood vessels, thus, damaging them. This would also lead to something much worse, which is when calcification reaches the arterial media. This problem is referred to as calcifilaxis, which is a heavy contributor to the morbidity and mortality of ESRD patients (Milazi, Bonner, & Douglas, 2017).

Among the problems identified were pill burden, which most of these patients have from needing to take numerous amounts of medications each day (Umeukeje et al., 2015). In addition, each patient also has personal barriers concerning their health beliefs such as their perceive vulnerability to ailments (University of Twente, 2017). Some of these patients would not change until they develop symptoms severe enough to affect them on a daily basis. The DNP student had seen patients who do make any constructive change even after getting hospitalized and after explaining to them the link between their behavior and their illness. And it is painful to see them struggling and suffering from having a lack of motivation to take care of themselves and be less receptive of education their care providers give them.

Project Design

The strategy was rapid improvement cycle done through a pilot study, which can be used on a larger scale later. Adult outpatient hemodialysis patients will be evaluated after one month of interventions. This was conducted at a small scale at the dialysis clinic where the DNP student works. This clinic has 48 chairs for outpatient hemodialysis per shift, with 3 shifts per day. 48 chairs are divided into 3 stations with 1 nurse assigned for each station, along with a patient care technician (PCT) assigned with a maximum of 4 patients per shift. Thus, usually, there are 3 nurses, one of which is the charge nurse and 6 PCTs. There is also a registered dietician at the clinic.

The reason for choosing this setting, other than the obvious reason of it being a dialysis clinic, was due to it having patients struggling to adhere to their phosphorus control, and adequate staff to carryout interventions. The clinic also has electronic health records(EHRs) that can be used to keep track of patients' progress. The current patient census of the clinic is 112.

The participants were determined based on the trend of their serum phosphorus level. Those who have a persistently elevated serum phosphorus level of more than 5.5 mg/dL within a period of three months were included in this project. There were 32 participants that were interviewed to determine the barriers faced in trying to adhere to a phosphorus control regimen (diet and medications) and also to determine what motivated and/or what would motivate them in taking their phosphate binders and adhering to their prescribed diet (Milazi, Bonner, & Douglas, 2017).The HBM guided the interview process.

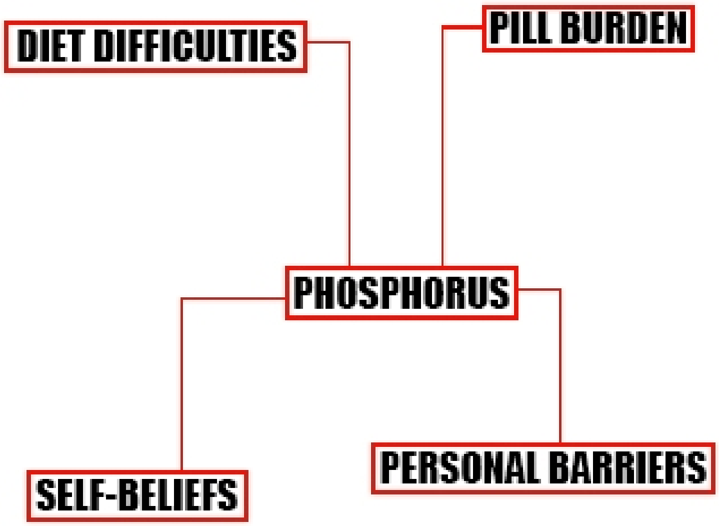
The DNP student and the dietician assessed patients with high phosphorus as noted in the EHR to determine who would need to receive a motivational approach to improve phosphorus levels. A total of 32 patients were determined to be eligible for the project. Motivational interviewing was done to gather data from patients. The data gathered included what motivates patients, reasons for discouragement, personal view of phosphorus, knowledge of phosphorus, belief and view of hyperphosphatemia, perceived vulnerability, and other personal barriers. Learning what they think they could do to manage their serum phosphorus, how they can manageit better, what would motivate them to manage their serum phosphorus or how to do it better, their confidence in their ability, and their readiness to take action guided the creation of individualized plans (University of Twente, 2017).The data gathered were used to create an individualized approach rather than a blanket approach. For example, if a patient was having pill burden, then using a pill organizer big enough to cover one week could encourage taking medications in a timely manner, thus decreasing burden (Chiu et al., 2009). Approaches were created by the DNP student. This allowedfor a more comprehensive, well-thought-out plan. The serum phosphorus results prior to and after interventions were compared.

Interventions to motivate these patients such as giving rewards like candy or new pill boxes were used, depending on the degree and consistency of improvement. Motivational interviewing was implemented through the methods of McCarley (2013) in which identification of medication-taking behavior was assessed, as well as reasons for not taking or missing/skipping medication doses, and the degree of pill burden. A major goal of the interviews was to determine how these patients try to manage their phosphorus levels, with promotion of self-management being a priority in addition to education.

Project Plan

The project plan was carried out as follows:

1. Conducted an assessment of those that had a trend of high phosphorus results. This determined the ones that would need to receive a motivational approach to improve their serum levels. The clinic's EHR was used for this step and for evaluation.
2. The DNP student and the dietician conducted motivational interviewing to gather data from patients and, at the same time, to provide encouragement/motivation. This helped facilitate interventions and plan sustainability. The data gathered includedwhat motivates patients, reasons for discouragement, personal view of phosphorus, knowledge of phosphorus, belief and view of hyperphosphatemia, perceived vulnerability, personal barriers, what they (patients) think they could do to manage their serum phosphorus, how they are managing their serum phosphorus, if they are not managing their phosphorus and why not, what would motivate them to manage their serum phosphorus or how to do it better, their confidence in their ability, and their readiness to actually take action (University of Twente, 2017).



3. The group of target patients was divided between the DNP student and the dietician. This way, the task would be more organized and consistency would be maintained by having patients be addressed by the same care provider.
4. The data gathered were used to create an individualized approach not a blanket approach according to the current practice of individualized patient care. For example, if a patient is suffering from pill burden, then having a pill organizer big enough to cover one whole week might encourage taking medications timely, thus decreasing burden (Chiu et al., 2009).
5. Individualized motivational approaches were created by brainstorming among the DNP student, the dietician, and mentor. This allowed a more comprehensive, well-thought-out approach.
6. The DNP student and the dietician implemented individualized, motivational approaches to the assigned patients to maintain consistency with established rapport.
7. The serum phosphorus results prior to and after interventions were compared.

Outcome evaluation.

The evaluation of the success of this project was assessed through the patients' serum phosphorus results using an electronic health record (EHR) program being utilized at the clinic. Serum phosphorus level is included in the clinic's monthly blood draw. The clinic's EHR program can show serum phosphorus trends and highlights abnormal results. Results were measured a month from implementation.Interviewing the patients was also done to assess how interventions affected them in managing their serum phosphorus. This helped determine if it made managing it easier or more complicated with the goal of improving future interventions and approaches.

Procedures for data collection.

The DNP student consulted with the clinic’s manager regarding protection of patient privacy and had a health insurance portability and accountability act (HIPAA) form signed prior to the start of the project. Protected personal information remained anonymous for the result of the project. The DNP student collected laboratory results prior to interventions to establish a baseline. Data gathered from the patients were obtained through motivational interviewing based on McCarley's (2013) guidelines.

Data were collected through motivational interviews and laboratory results from the EHR. Interviews and follow-ups were done weekly, while laboratory results will be monitored after a month, since the blood draw which includes phosphorus was done monthly. Assessment findings from interviewing and most recent phosphorus results were gathered prior to interventions to have a baseline for each patient.

Evaluation and sustainability plan.

Patients' motivation was evaluated on a weekly basis in terms of if they were able to follow their individualized plan (i.e. if they missed doses and why) and if it complicated their routine, and their ability to keep up with changes from interventions. Weekly motivational interviewing and modification of interventionswere done to prevent regression and maintain progress as much as possible. A weekly meeting with the dietician took place to also promote patient progress. Data gathered were discussed and appropriate grouping of interventions were tackled to create individualized plans of care. And since patient hemodialysis schedule varies from Mondays, Wednesdays, and Fridays (M-W-F) and Tuesdays, Thursdays, and Saturdays (T-TH-S), weekly meetings were done every Thursday or Friday depending on the shift of the DNP student and the dietician.

Informed consent process

The DNP student explained the purpose, goals, methods, and how the confidentiality of the subjects would protected in a private area. They were informed that the data collected would not reveal their identity and they would be assigned a number instead. There was no video or voice recording during motivational interviews. The subjects were asked to sign an informed consent form. They wereinformed that they could refuse or stop participating before or anytime during the course of the research, and that it would not affect the treatments they receive at the dialysis clinic. They were asked not to talk to people about what was said during the interviews and keep it confidential. However, they were also informed that they, under their own discretion or freewill, could not be stopped to share information that should be confidential.

Data Analysis

The DNP student entered the data gathered using Microsoft Word and Excel. The dietician, DNP student, and his mentorwere responsible for analysis of the data. This way, corrections could be made to minimize the risk of mistakes as the project implementation progresses.Patients' serum phosphorus levels before and after interventions were compared. Analyses of processes or how interventions were implemented was done to adjust interventions according to the data gathered for each patient (Harries,Roussel, Dearman, & Thomas, 2016). Quality of outcome was evaluated according to comfort of patients, consistency of results, and serum phosphorus trend after interventions. Quantitative analysis was conducted after a month from implementation to determine how much improvement occurred in the patients' phosphorus levels.

Ethical Issues

The DNP student obtained informed consent from each patient prior to the start of the project. Subjects were informed individually about the purpose, aims, how their identities would be protected, risks and benefits, would not affect their treatments, and how their information such as identifiers and blood samples would be protected, and that the research team members would be the only ones who would see the data collected. Participation was voluntary and the subjects could withdraw at any timeduring this study. Their participation was to be kept confidential along with their identities. The data collecteddid not reveal their identities in any form. Their personal beliefs and preferences were treated with utmost respect, along with being sensitive both morally and culturally when conducting this project.

Subjects were asked not to share information with other patients. The data or information collected during interviews was not to be shared with anybody outside the research team, and nothing would be attributed to subjects by their name. The subjects were identified through a number system alongside their phosphorus results in order for their identities to remain confidential.

Institutional Review Board Approval

The project received approval by the IRB committee of Washington University School of Medicine, with an articulation agreement with Committee on the Use of Human Subjects in Research of Bradley University. See Appendix D.

Chapter IV: Organizational Assessment and Cost Effectiveness Analysis

Organizational Assessment

The clinic has been constantly trying to come up with new ways to help patients improve their serum phosphorus level. The clinic’s manager and staff, which include the dietician and the DNP student’s mentor, eagerly anticipated and strongly supported the implementation of this project. They have shown enthusiasm and willingness to support this project plan. This DNP project also abides by the institution's mission and vision. The project was congruent with the mission of advancing human health through best care, inventive research, and education of future leaders that reinforces diversity, inclusion, critical thinking and creativity (WUSM, 2018), and vision of promoting excellence, outstandingly creative research, and the application of research advances for better care.

The anticipated barriers included the patients’ inability or unwillingness to participate.Chronic renal disease is the disease of non-compliance, something that usually results from not adhering to hypertension and diabetes management. Therefore, having the support of the clinic’s manager, lead charge, dietician, and the DNP student’s mentor, which is one of the nephrologists working at the clinic, provided a solid support to this project. The DNP student collaborated with the dietitian and nephrologist in implementing this project. Other possible barrier was the patient access to the appropriate diet, whether it was secondary to unavailability or excessive cost.

Cost Factors

There is an EHR being utilized at the clinic to monitor serum phosphorus levels. The DNP student and the computers at the clinic have Microsoft Word, Excel, and computer software to edit videos and create images already at hand. The staff needed to implement this project also works at the clinic. The DNP student works 14-hour shifts 3 times a week, the dietitian works 8 hours a day for 5 days each week, while the mentor rotates with two other nephrologists. The presence of tools and staff needed for this project's implementation avoided extra costs, since the time spent interviewing and developing individualized approaches took the place of normal patient education time. It took one month for implementation and evaluation of phosphorus results, and which the project team kept track of actual cost. The implementation of this project resulted in similar amounts of time spent with educating patients and was not wasted, sincemotivated patients were keen to learning. Better outcomes would result in fewer hospitalizations and readmissions, thus resulting to them being at the clinic for treatment more and living their lives outside afterwards. This means more reimbursement for the clinic due to the patients having better health outcomes. All the necessary resources and tools were already present at the clinic.

Chapter V: Results

Outcomes

The project implementation was very complex due to the fact that this was an individualized approach. However, the initiation was virtually the same for all the 32 subjects. Patients with a phosphorus average of higher than 5.5 mg/dl within the last 3 months prior to April were asked to participate in this project. The reason for this was that the DNP student, initially, had to thoroughly explain what this project entailed for them, what they could expect, risks and benefits, and how it would be slightly personal in order to pinpoint their actual difficulty or issue regarding phosphorus control. The initiation of this project revolved around informed consent, in addition to the targeted benefits of having a consistently acceptable serum phosphorus level between 2.7 to 5.5 (Kalantar-Zadeh, 2013).

The subjects went through 4 days of motivational interviewing. These were done 1 day per week for the total of 4 meetings. The clinic has 3 shifts for patients, which are the ones that come in early in the morning (0520-0630), mid morning and noon (0900-1130), and early to mid afternoon (1300-1500). The first meeting took the longest and was where questions related to what the subjects know and believe about phosphorus, consequences they believe or know from having consistently high levels, when they were taking their phosphate binders, and if they knew which foods to avoid. In addition, and if applicable,they were asked by the DNP student if their family helps them manage their diet or remind them when to take their phosphate binders. Most of the subjects had a similar problem, which was when they were taking their binders. For example, some of them were taking their phosphate binders with the rest of their medications early in the morning instead of immediately prior to eating breakfast. Such medications are best taken immediately before a meal to receive their full effect (Milazi, Bonner, & Douglas, 2017). Meanwhile, most were taking their binders 30 minutes or more before and after eating. The other subjects stated that they often forgot to take their binders entirely.

The DNP student suggested using empty medication bottles to contain a few of their binders, so they could take some when eating out. This was especially emphasized with the subjects that ate out more often than at home. Those who ate at home often were advised to place their bottle of binders at the center of their dinner table, provided that there were no children present at their homes. This helped remind those who often forget to take their medications to take them as they have their meal, because they would see them and be reminded to take them. They were also encouraged to let their family members help remind them to take their binders. Only a select few took notes of what the dietician taught them to avoid eating. Diet would be the best way to manage their phosphorus levels and is the main issue. However, not taking their phosphate binders at the right time and/or forgetting to take them made it more problematic for them.

Due to the one month time frame, there were only minor changes for some of the subjects to be able to focus better during the 1-month implementation process. During the second and third week, the DNP student and each subject worked on identifying foods low and high inphosphorus, and then decided which the subjects were comfortable avoiding. Most of them identified cheese as subjects were followed up during the second, third, and fourth week. They were asked if they had questions about phosphorus management and if they were able to keep up with their binders. The main focus was on the binders for most of the subjects, since most of them were not ready for more diet modifications. Minor adjustments were made in terms of taking their binders.

There were 32 subjects that participated in this project. As shown in table 1.1, two subjects' results (6.06%) were labeled as neutral due to their phosphorus level staying the same from their results back in the first week of April compared to their results on the first week of May. Seventeen subjects (51.51%) had higher results and 13 subjects (39.39%) had improved or had results within acceptable range (<5.5 mg/dl). The subjects who had higher results in May compared to April admitted to sometimes forgetting to take their phosphate binders, even though they did admit that they tried to avoid eating foods high in phosphorus.That was addressed, as previously stated, by placing their pill container at their dinner table if children were not present. In addition, for those who eat out a lot to place small amounts of binders in small containers that can easily fit in their pocket.On the other hand, 13 subjects had improved results. They stated having taken their binders right before they eat without missing a dose during the 1-month implementation. Some of them even tried avoiding other foods high in phosphorus other than cheese, which is what they commonly knew as being high in phosphorus.

A T test was done with Welch's correlation to analyze changes. The subjects' 3-month phosphorus average was compared to their results in May, which had no statistical significance as evidenced by a P value of 0.70 (>0.05), with F test having a P value of 0.17 (>0.5). The comparison of their April and May results were also insignificant with Welch's correlation showing a P value of 0.06 (>0.05), and a P value of 0.06 (>0.5) with F test comparing variances. The insignificance in change would be due to factors that would include length of implementation and sample size. Although the participants' phosphorus results after interventions were insignificant, they did show increased knowledge and motivation regarding phosphorus management as evidenced by asking questions, tips, and techniques during interview sessions.A long-term implementation could effectively change their motivation and behavior.This was because of the chronic nature of hyperphosphatemia with chronic renal disease. It would require six months to one year to achieve a major change in behavior.

	3 MO Ave Phosphorus	April Phosphorus	May Phosphorus
1	5.6	5.6	🟥 6.4
2	6.8	7.5	🟩 6
3	8.8	9.9	🟩 7.1
4	7.2	7.5	🟥 8.5
5	6.5	5.1	🟥 6.3
6	8.8	8.9	🟥 9.4
7	5.6	6.6	🟩 4.9
8	6.6	5.6	🟥 6.9
9	8.5	6.4	🟥 8.8
10	6.3	7.4	🟥 8.8
11	8	8.6	🟥 9.7
12	5.7	4.4	🟩 5.3
13	6.2	6.8	🟥 7.4
14	6.9	6.7	🟩 5.8
15	5.7	6.2	🟩 5.5
16	6.2	5.5	🟥 5.8
17	5.7	5.3	🟩 5.5
18	7.3	5.7	🟥 6.8
19	9.7	8.1	🟥 9.1
20	5.7	3.7	🟩 4.9
21	6.4	6.4	🟥 7.4
22	6.2	6.9	🟥 7
23	7.2	5.8	🟥 6.8
24	5.9	6.6	🟩 6.3
25	7.7	6.9	🟨 6.9
26	7.3	5.9	🟥 6.7
27	6.1	8.6	🟩 6.8
28	6.1	5.9	🟥 6.3
29	5.7	5.3	🟩 5.4
30	8.4	9.7	🟨 9.7
31	6.9	9.7	🟩 8.1
32	6	6.2	🟩 5.3
	🟩 Improved or within Normal Range	🟨 Neutral	🟥 Increased
	13	2	17
	40.62%	6.25%	53.12%

Table 1.1

Table Analyzed	Data 1
Column B	After
vs.	vs.
Column A	3 months before
Unpaired t test with Welch's correction	
P value	0.703
P value summary	ns
Significantly different (P < 0.05)?	No
One- or two-tailed P value?	Two-tailed
Welch-corrected t, df	t=0.3832 df=58.51
How big is the difference?	
Mean ± SEM of column A	6.803 ± 0.1955, n=32
Mean ± SEM of column B	6.925 ± 0.2509, n=32
Difference between means	0.1219 ± 0.3181
95% confidence interval	-0.5147 to 0.7585
R squared (eta squared)	0.002503

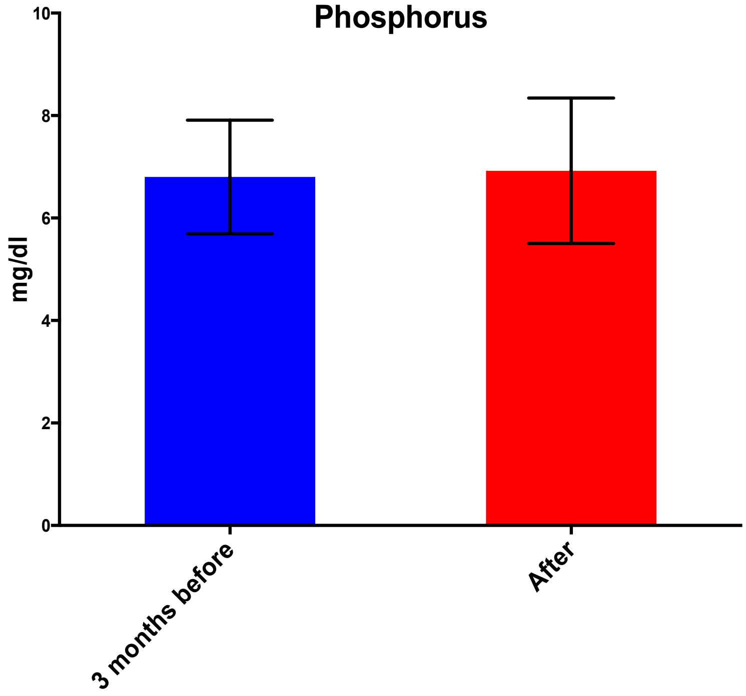


Table 1.2

Table Analyzed	Data 1
Column B	After
vs.	vs.
Column A	Before
Unpaired t test with Welch's correction	
P value	0.6013
P value summary	ns
Significantly different (P < 0.05)?	No
One- or two-tailed P value?	Two-tailed
Welch-corrected t, df	t=0.5253 df=61.66
How big is the difference?	
Mean ± SEM of column A	6.731 ± 0.2704, n=32
Mean ± SEM of column B	6.925 ± 0.2509, n=32
Difference between means	0.1938 ± 0.3688
95% confidence interval	-0.5436 to 0.9311
R squared (eta squared)	0.004456

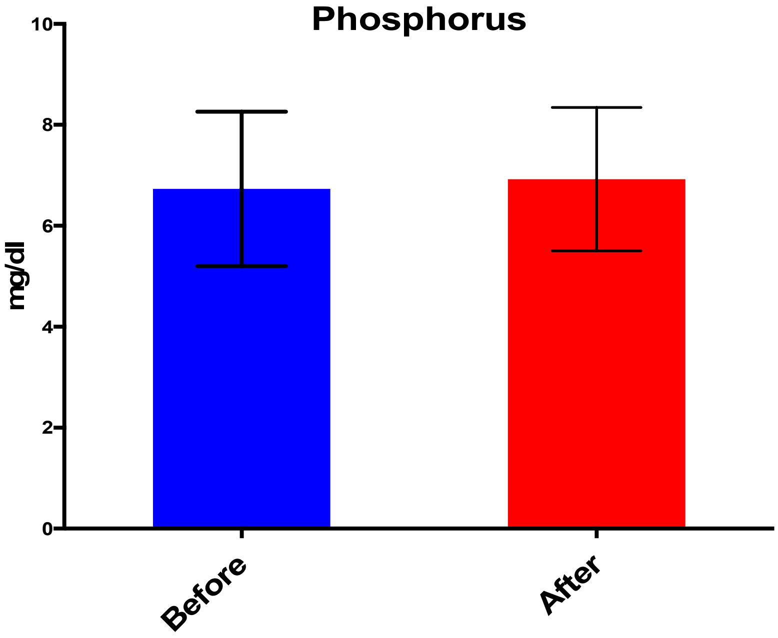


Table 1.3

Chapter VI: Discussion

The main change in care delivery was the weekly follow up done through a motivational approach during implementation. This encouraged the subjects to be more involved with their care, in this instance, their phosphorus management regardless of their serum phosphorus results.This was the greatest success of the project. Getting their involvement through encouragement made it easier to educate them on a weekly basis. And because of the individualized approach of this project, none of the subjects felt nagged or annoyed, rather, they felt genuine concern and respect without feeling pressured to change.

The major hurdle for this project were having missed doses in several subjects due to them forgetting to take their binders or not having any when eating meals out and/or having a snack. Establishing rapport was never a problem for the DNP student to establish due to being a staff nurse at the dialysis clinic this project was performed. The interventions were effective in getting the subjects to be concerned about hyperphosphatemia and its effects on their health, encouraged them to start or put more effort in phosphorus management, and had them to be more involved in their own care as evidence by asking meaningful questions.

Limitations of the project plan were due to the time span of interventions, which was 1 month. It would be interesting to see if interventions would have been implemented for at least 6 months to see further change in results through motivating subjects with their individual phosphorus management. One thing seen to have been lacking in this project was further intervention for subjects that had more trouble remembering to take their binders. And although they were advised to place the container for their binders on top of their dinner table or carry them around in a smaller pill container. They could have benefited by having a small pocket check off calendar, which could have also further helped them remember to take their binders. This could help them further get into the habit of taking them on time and not forget to take them less often or eliminate such.

Motivational approach to help adults undergoing outpatient hemodialysis does not go beyond the current standards of care and does not cost anything, since all it requires are already present in dialysis clinics. Such interventions also does not require hiring additional staff, since nurses, patient care technicians, and the dietician can all help patients with their phosphorus management.Therefore, the addition of such interventions would not be complicated, considering they are simply a weekly follow up with patients to help them manage their phosphorus. Nephrologists at the clinic also educate and remind patients about the importance of taking their binders.In addition, dialysis staff from all levels are familiar with phosphorus and how phosphate binders work, thus rigorous training that would otherwise cost money for a clinic would not be necessary. Adding such will only require assigning roles and additional information during scheduled staff meetings.

Opportunities for interdisciplinary collaboration during this project were between the DNP student, nephrologist, and the clinic’s dietician. The dietician provided insight as to what adults undergoing outpatient hemodialysis typically struggle with phosphorus management, which is commonly rooted to medication adherence and diet. The nephrologist helped guide the path of this scholarly project though his knowledge of how hyperphosphatemia affect hemodialysis patients both short and long term, in addition to how pill burden, self-belief, and family structures affect their adherence to phosphorus management.

The findings of this project suggest that following up with patients who have consistently high phosphorus at least once a week would prove to have changes through individualized approaches long-term through increased motivation and understanding of phosphorus control(Milazi, Bonner, & Douglas, 2017). Hemodialysis nurses have the knowledge and ability to motivate, education, and follow up with their assigned patients that can be made as a weekly task by the clinic manager.This kind of endeavor can be easily implemented due to it being not time consuming and cost effective. Advanced Practice Nurses (APN) and nephrologists can further enhance a patient's OLOF by incorporating motivational approach during their outpatient rounds, and help formulate plans that are less complex yet significantly more effective. And pill burden, being one of the reasons such patients become less motivated to religiously take their binders, means that nurses have the means to help them instead of getting prescribed more medications to take.

There was no identified health care policy that goes against this project, because it does not go over current standards of care. This project magnifies a current problem and draws more focus to it in order to address such a problem with meaningful solutions for each patient. It does not go against the workflow of nurses, because it is not time consuming to follow up with a few patients that have hyperphosphatemia that can be spread throughout a work week.It should be imperative for every dialysis clinic to give hyperphosphatemia a great deal of focus due to its debilitating long-term effects that leads to a poor quality of life from severe itching, pain (mild to severe) during ambulation, and requiring frequent hospitalization due to organ damage. This project clearly finds that each hemodialysis entity needs to incorporate in their policy that their staff should help patients struggling with phosphorus management through a weekly follow up to motivate and educate, and with the creation of individualized plans on assigned patients by collaborating with dieticians and nephrologists.

Chapter IV: Conclusion

In conclusion, there remains a gap in both educational and motivational approach in trying to improve adult hemodialysis patients' adherence to phosphorus control. This with particular attention to motivation from staff to encourage patients to adhere, improving self-motivation in the process. The strength of the evidence that there is still a problem is proven by the fact that a lot of adult hemodialysis patients are either struggling or do not care enough to manage their phosphorus intake, let alone take their binders. There are available tools that can be used to measure outcomes of interventions and tools to help staff in aiding patients to better manage their phosphorus. Based on current evidence, further investigation is needed and will be explained further. What is currently known and also a limitation to this study is the lack of standardized tools that are mandated to be used in every hemodialysis clinic (Milazi, Bonner, & Douglas, 2017). Current literature and studies answered the question of whether educational and motivational approach would gain better results than just educating adult hemodialysis patients in improving their phosphorus control adherence. Every entity seems to just create its own plan, which more often than not, based on my experience, are not comprehensive.

Often times, hemodialysis clinics simply educates patient, seldom asking what a patient specifically struggles with, and/or even give up in trying to help a non-compliant patient, which are prevalent in the outpatient hemodialysis setting. Reinforcing the knowledge of patients on top of constant education should also be done in order to be consistent. Approaches have been done in classes for groups of patients, but there still should be an individualized, interactive approach, and not just handing out instructional materials to each patient. One recommendation will be to help patients arrange their medications in a one-week pill container, which have shown positive results. It relieved some of the confusion and burden from taking so many pills in a day.

Educating hemodialysis staff with current information will help with consistency and efficiency of individualized intervention. Such an education for staff should not be done through an online learning module, because more often than not, staff simply click through modules to get it over with. Itshould be done in a classroom setting to be more effective.Recommending that hemodialysis nurses be actively involved in educating and motivating patients and not just rely on the dietician(s) to help patients with their phosphorus control management. Managers of hemodialysis clinics should require staff to educate their primary patients that struggle with their phosphorus control at least monthly until their serum phosphorus level goes back to the normal range.The DNP student filled a gap in approach with this project in addition to gaining more evidence and to created better interventions in improving adult hemodialysis patients' phosphorus control for them to have better outcomes. Interventions done through an individualized approach to increase patient motivation, reception to education, and their initiative to manage their phosphorus according to recommended dietary restrictions and prescribed medications.

During the implementation of this project, Doctor of Nursing Practice (DNP) Essential I was met through the utilization of knowledge and insight into the struggles with phosphorus management faced by adults undergoing outpatient hemodialysis (American Association of Colleges of Nursing [AACN], 2006). In addition to identifying patterns of human behavior when it comes adherence based on their self-beliefs, perception of susceptibility, and what drives them to take steps towards preserving their optimum level of function instead of deteriorating. DNP Essentials II and III were met through the focus of improving patient outcomesan expert level of knowledge gained from research and mentorship. Evaluation of care delivery approaches were done in order to create appropriate individualized plans, lead quality improvement, analysis of cost effectiveness of the project, and developed and evaluated effective evidence-based approaches prior to and during implementation. DNP Essential IV was realized through the EHR software used by the clinic to evaluate the each subject's phosphorus level and its trend.

DNP Essential V was shown when the DNP student analyzed current health care policy at the dialysis clinic and if current standards of care were sufficient enough in creating a project to take on an ongoing patient issue of low patient adherence to phosphorus management (AACN, 2006). The continued collaboration with a nephrologist and a dietician benefited DNP Essential VI, because their valuable input, support, and guidance throughout this project helped with its development. The success of this project will definitely lead to an expanded version to cover more variables and similar problems patients with renal disease face. The problem this project took on is present in a lot of patients in every dialysis clinic causing poor long-term outcomes for those affected, which covers DNP Essential VII by considering concepts related to individual and population health, as well as cultural and socioeconomic dimensions of health.Lastly, DNP Essential VIII was shown by incorporating culturally sensitive approaches in terms of this project's design, implementation, sustaining therapeutic relationships with subjects. In addition,partnership with subjects, dietician, and nephrologist were established.

The DNP student plans to present this scholarly project through an online video presentation hosted by Bradley University in Peoria, IL. This will be submitted through Doctors of Nursing Practice Doctoral Project Repository after a successful presentation. This project helped the DNP student realize goals such as knowing advanced concepts of health, evaluation of current health care policies and standards, how to improve health care delivery in this chosen topic, and how to properly conduct a research project.The DNP student achieved the level of guidance from his mentor and professor he would need for professional development by gaining better clinical judgment and understanding of diverse populations and their needs.

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Appendix

Appendix A: Project Timeline

Project Phase	**Milestone**	**Mar**	**Apr**	**May**	**June**
Initiation	Project charter approved	**x**			
Planning	Project planning approved		**x**		
	Project plan completed	**x**			
	Communication plan completed	**x**			
	IRB approved		**x**		
	Hardware and software approved	**x**			
Implementation	Training completed		**x**	**x**	
Monitoring	Mid-project evaluation complete			**x**	
Closing	Project completion meeting				**x**

Appendix B: Tools

Motivational interviewing tool by McCarley (2013).

	Education	**Self-management Promotion**
What is taught?	Specific information: 1. Phosphorus Goal 2. Identify high phosphorus-containing foods	Problem-solving skills significant to the effects of the disease: 1. Adverse effects of hyperphosphatemia 2. Ways to limit intake of foods high in phosphorus
How are problems identified?	Insufficient control of disease 1. Phosphorus out of normal range	Patient figures out the problem that may or may not be linked to the disease: 1. Busy with work or family 2. Consumption of processed foods
What is the goal?	Adherence with behavior change: 1. Phosphorus falls within normal limits	Accountability to enhance health outcomes: 1. Find out ways on how to easily cook foods low in phosphorus

Tools for self-management by McCarley (2013).

1. Teach back by asking patients to tell you what they know in their own words to check how well interventions were taught.
2. Motivational interviewing due to patients seldom motivated by education. This will require active listening and therapeutic communication to solve complex issues of patients. This will require focus on a patient's concern, reinforcing a patient's reason to change, and setting realistic and attainable goals in partnership with a patient.
3. Show empathy, avoid arguments and remain neutral and nonjudgmental, create discrepancy to set a patient's behavior from their goals, and nurture the belief of a patient that he/she will be able to achieve the goal of having a normal phosphorus level.
4. Ask open-ended questions and reinforce their positive answers.

Personal Action Plan & Self-Confidence Ruler (McCarley, 2013)									
I want to make a change in:									
My goal for this week is:									
The action I need to make to achieve my goal:									
Obstacles that could make it harder for me to reach my goal:									
How I plan to overcome these obstacles:									
My self-confidence ruler upon reaching my goal:									
1	2	3	4	5	6	7	8	9	10
Follow-up (achievements and obstacles):									

Appendix C: Budget Table

Program expenses

This section will be added and completed at the end of the project.

Startup costs.

Paper	$5
Pens	$2
Total Startup Costs	$7

Capital costs.

Computer	$0 (Own computer and work computer)
SPSS Software	$0 (Provided by Bradley University for free)

Operational costs.

Electricity	$0 (provided by clinic)
Heating	$0 (provided by clinic

Total Project Cost	$7

Appendix D: Informed Consent

INFORMED CONSENT DOCUMENT

Project Title: Motivational Approach to Improve Adherence to Phosphorus Management in Adults Undergoing Outpatient Hemodialysis

Principal Investigator: Ian Villanueva

Research Team Contact: **Ian Villanueva - 314-409-9968**

Dr. George Jarad, MD - 314-286-0800

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights and responsibilities as a research participant. By signing this form you are agreeing to participate in this study.

- You should read and understand the information in this document including the procedures, risks and potential benefits.
- If you have questions about anything in this form, you should ask the research team for more information before you agree to participate.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because youare an adult undergoing outpatient hemodialysis needing ways to improve your phosphorus to achieve better health outcomes.

We want to find ways in improving patient motivation to better control phosphorus levels, which if left unmanaged, will significantly increase complications associated with it. We believe that you can help us develop motivation-based plans by participating in this project. We want to learn what motivates patients in managing their phosphorus levels and how effective such an approach can be. This knowledge might help learn how to better control phosphorus in this patient population.

WHAT WILL HAPPEN DURING THIS STUDY?

[Describe the following:

- **What is going to happen to the participant as part of this study**

We are asking you to help us learn more about ways to improve phosphorus control through motivational means for adult patients undergoing hemodialysis. We are inviting you to take part in this research project. If you accept, you will be asked to take part in interviews with a researcher concerning what motivates you to control your phosphorus level and your self-belief of having high levels of phosphorus in the blood. We will make surethat you are comfortable. We can also answer questions about the research that you might have. Then we will ask you questions about high phosphorus blood levels and give you time to share your knowledge. You are allowed to skip questions that you do not feel like answering. We will ask youto share personal beliefs, practices or stories, but you do not have to share any knowledge that you are not comfortable sharing.

The interviews will take place during one of your dialysis days at Forest Park Kidney Center every week for 1 month, and you will not be contacted from home during this research. The entire conversation will not be video or voice recorded. The data collected will be documented in writing and you will not be identified by name. The data collected will not reveal your identity.

The research is 1 month long. During that time, we will interview you once a week during one of your dialysis days. Each interview will last 30 minutes to 1 hour.

Will you save my research data to use in future research studies?

As part of this study, we are obtainingdata from you. We would like to use thisdata for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding motivational approaches to improve patient outcomes. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you for use of your data. By allowing us to use your data you give up any property rights you may have in the data.

We will share your data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or commercial sponsors of research. We may also share your data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

If you change your mind and do not want us to store and use your data for future research, you should contact the research team member identified at the top of this document. The data will no longer be used for research purposes. However, if some research with your data has already been completed, the information from that research may still be used. Also, if the datahas been shared with other researchers it might not be possible to withdraw the datato the extent it has been shared.

Your data will be stored without your name or any other kind of link that would enable us to identify what data is yours. Therefore, it will be available for use in future research studies indefinitely and cannot be removed.

Please place your initials in the blank next to Yes or No for each of the questions below:

My data may be stored and used for future research as described above.

_____ Yes _____ No

Initials Initials

My data may be shared with other researchers and used by these researchers for the future research as described above.

_____ Yes _____ No

Initials Initials

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 50 people will take part in this study conducted by investigators at Washington University.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for 1 month. During that time, we will interview you once a week during one of your dialysis days. Each interview will last 30 minutes to 1 hour.

WHAT ARE THE RISKS OF THIS STUDY?

- We are asking you to share with us personal beliefs and habits involving how you manage your phosphorus. You may feel uncomfortable talking about some of the topics. You do not have to answer any question or take part in the interview if you do not wish to do so, and that is also fine. You do not have to give us any reason for not responding to any question or for refusing to take part in the interview. Otherwise, there will be no physical risks from this study involving motivational approaches.

[Breach of Confidentiality]

One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure. Please see the section in this consent form titled *"How will you keep my information confidential?"* for more information.

WHAT ARE THE BENEFITS OF THIS STUDY?

There will be a direct benefit to you if interventions are successful in helping you manage your phosphorus. Your participation is likely to help us find out more about how to help adult patients undergoing hemodialysis better control their phosphorus through motivational approaches.

We hope that, in the future, other people might benefit from this study because what we will learn from this research will also help more patients in a similar situation, as well as improve the quality of care.

WHAT OTHER OPTIONS ARE THERE?

This research is about improving adherence you currently have through motivation done through interviewing.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?

The University and the research team are not receiving payments from other agencies, organizations, or companies to conduct this research study.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?

We will keep your participation in this research study confidential to the extent permitted by law. We will not be sharing information about you to anyone outside of the research team. The information that we collect from this research project will be kept private. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is. It will not be shared with or given to anyone except Darlene Nichols, RD; Dr. George Jarad, MD; and I, Ian A. Villanueva.

We will ask you and other patients included in this research not to talk to people about what was said during the interviews. We will, in other words, ask each of you to keep what was said confidential. You should know, however, that we cannot stop or prevent participants from sharing information that should be confidential.

Other than the research team.Washington University's Institutional Review Board (a committee that oversees the conduct of research involving human participants) and Human Research Protection Office. The Institutional Review Board has reviewed and approved this study.

Any report or article that we write will not include information that can directly identify you. The journals that publish these reports or articles require that we share your information that was collected for this study with others. Sharing this information will allow others to make sure the results of this study are correct and help develop new ideas for research. Your information will be shared in a way that cannot directly identify you.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. Any data that was collected as part of your participation in the study will remain as part of the study records and cannot be removed.

If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I decide to withdraw from the study?

You may withdraw by telling the study team you are no longer interested in participating in the study.

Will I receive new information about the study while participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can someone else end my participation in this study?

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: **Ian Villanueva 314-409-9968.** If you feel that you have been harmed in any way by your participation in this study, please contact Dr. **George Jarad, MD at 314-286-0800**.

If you have questions, concerns, or complaints about your rights as a research participant please contact the Human Research Protection Office at 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed copy of this form.

Do not sign this form if today's date is after $STAMP_EXP_DT.

____ ________________________________

(Signature of Participant) (Date)

____

(Participant's name – printed)

Statement of Person Who Obtained Consent

The information in this document has been discussed with the participant or, where appropriate, with the participant's legally authorized representative. The participant has indicated that they understand the risks, benefits, and procedures involved with participation in this research study.

____

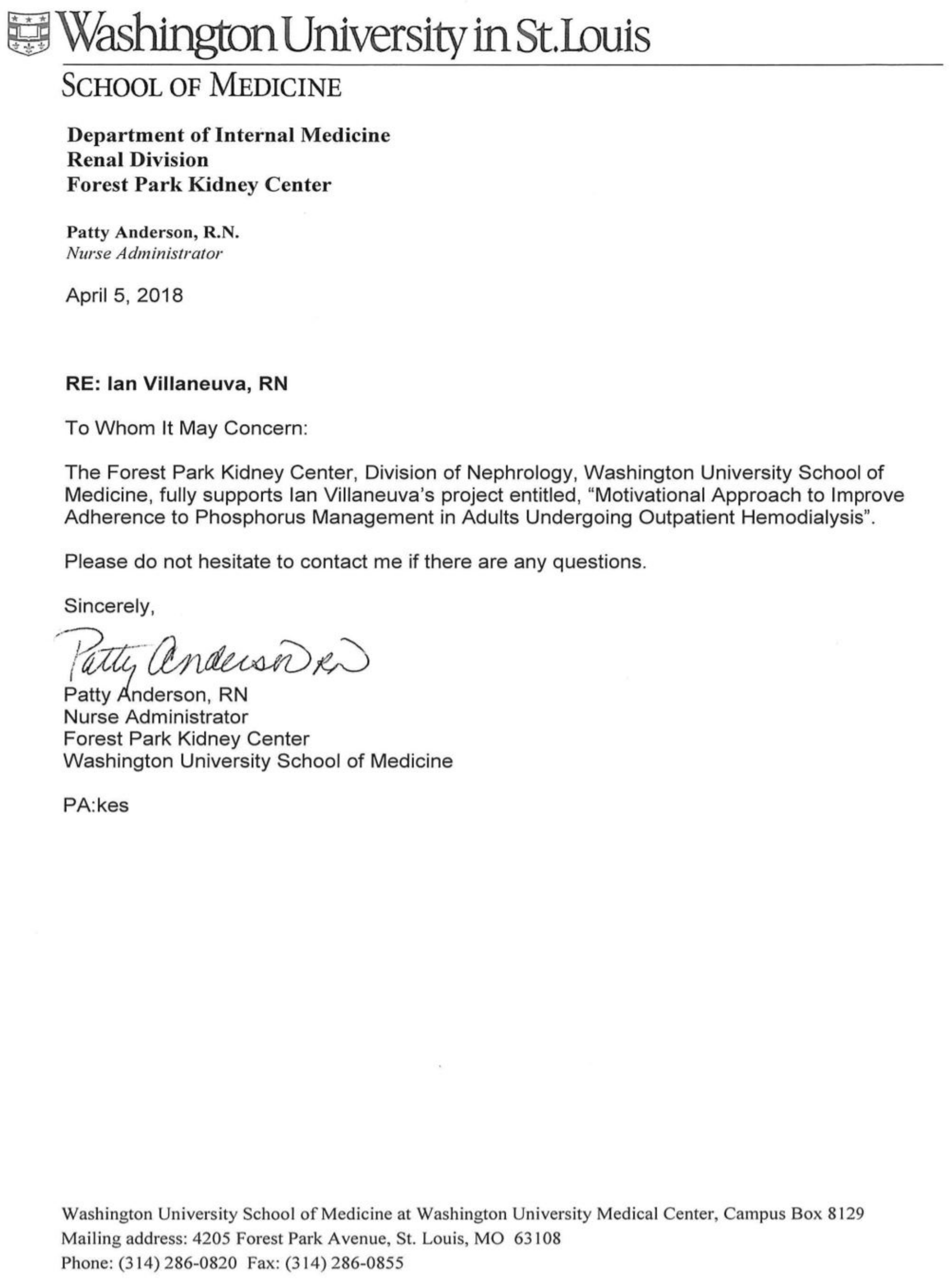
____

(Signature of Person who Obtained Consent) (Date)

____

(Name of Person who Obtained Consent - printed)

Appendix E: Letter of Approval



Washington University in St.Louis
SCHOOL OF MEDICINE

Department of Internal Medicine
Renal Division
Forest Park Kidney Center

Patty Anderson, R.N.
Nurse Administrator

April 5, 2018

RE: Ian Villaneuva, RN

To Whom It May Concern:

The Forest Park Kidney Center, Division of Nephrology, Washington University School of Medicine, fully supports Ian Villaneuva's project entitled, "Motivational Approach to Improve Adherence to Phosphorus Management in Adults Undergoing Outpatient Hemodialysis".

Please do not hesitate to contact me if there are any questions.

Sincerely,

Patty Anderson RN

Patty Anderson, RN
Nurse Administrator
Forest Park Kidney Center
Washington University School of Medicine

PA:kes

Washington University School of Medicine at Washington University Medical Center, Campus Box 8129
Mailing address: 4205 Forest Park Avenue, St. Louis, MO 63108
Phone: (314) 286-0820 Fax: (314) 286-0855