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Foot Assessment In the Dialysis Unit

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FOOT ASSESSMENT IN THE DIALYSIS UNIT

by

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DEDICATION

I would like to dedicate this research project to my family, friends, and patients. Thank you for your time, patience, and devotion.

ACKNOWLEDGEMENTS

I would like to thank the many people who saw me through this research project; to all those who provided support and listened to me complain when things did not go my way. I would like to thank Dr. Culley, Dr. Burgess, and Dr. Tavakoli for all their hard work and keeping me on task. How many times did you read and reread this project? I would like to thank the physicians and staff at Carolina Nephrology for all their support and encouragement---thanks Sally and Cindy for changing my schedule over and over. You guys are the best!

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I would like to thank my grandfather who did not live to see the completion of this project but is forever in my thoughts. I miss you.

Above all I want to thank my husband, Michael, my daughter, Kristiana, and the rest of my family, who supported and encouraged me in spite of all the time it took me away from them. I love you all.

ABSTRACT

In 2010 the number of patients requiring renal replacement therapy in the United States increased by 1% to 593,086. This number was comprised of 593,086 in center hemodialysis patients, 179,361 functioning kidney transplants, and 29,773 peritoneal dialysis patients.

A major complication in the end stage renal disease (ESRD) population is lower extremity amputation from vascular complications and nonhealing wounds. The incidence of nontraumatic lower extremity amputation among the end stage renal disease population in the United States is ten times higher when compared to the general public. Mortality rates for ESRD patients following amputation are elevated with less than 50% surviving two years postoperatively. Increased vascular complications force many amputees to undergo revisions to an amputated site, revascularization, or additional limb removal. Despite the increased mortality risk there is no lower extremity assessment guideline for ESRD patients. Unfortunately, the National Kidney Foundation does not require assessments to be performed even though early detection and prevention may potentially alleviate the need for amputation.

The purpose of this project was to analyze and synthesize current research regarding amputation risks in the ESRD population and implement a lower extremity assessment tool that can easily be performed in the hemodialysis unit. Following staff education, the quick assessment tool was placed into use at Upstate Dialysis in Greenville, SC. The dialysis nurses performed lower extremity assessments based on an

evidence based protocol for a period of three months on all dialysis patients with diabetes or over the age of 65 years. Vascular irregularities were noted on the assessment tool and referrals were made to wound management, vascular surgery, and podiatry as needed.

Findings demonstrated eleven new referrals were made to specialists in the three month period. These findings resulted in early recognition of complications including the need for a great toe amputation from osteomyelitis, a revascularization, and nine referrals for follow up care for potential complications. Recommendations from this translational quality improvement project include a standardized lower extremity tool for all hemodialysis patients, continued education for the staff and patients to identify potential lower extremity complications early, and ongoing research to decrease mortality risks in this population from vascular complications.

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LIST OF ABBREVIATIONS

AMI.....	Acute Myocardial Infarction
CHOICE.....	Choices for Healthy Outcomes in Caring for ESRD
CKD	Chronic Kidney Disease
CRP.....	C-Reactive Protein
CQI.....	Continuous Quality Improvement
CVA	Cerebral vascular accident
DOPPS	Dialysis Outcomes and Practice Patterns Study
ESRD	End Stage Renal Disease
GFR.....	Glomerular Filtration Rate
KDOQI.....	Kidney Disease Outcomes Quality Initiative
NIH	National Institutes of Health
NKF.....	National Kidney Foundation
PVD.....	Peripheral Vascular Disease
TIA.....	Transient ischemic attack
USRDS.....	United States Renal Data System

CHAPTER I

INTRODUCTION

After years of steady escalation the number of patients requiring renal replacement therapy in the United States displays a linear transition with only a slight elevation noted in 2010. According to the United States Renal Data System (2011), the initiation of new renal replacement patients in 2010 increased by less than 1% percent for a total of 116,946 individuals including 2,863 patients that received a preemptive kidney transplant. These additions increase the prevalence of renal replacement therapy patients to 593,086 with hemodialysis patients reflecting the greatest majority at 383,992 followed by individuals with a functioning kidney transplant at 179,361 and peritoneal dialysis patients at 29,773 individuals. The growth rate of 4 percent (compared to 2009) is the smallest increase in three decades.

Renal replacement therapy provides a life sustaining modality for many individuals in the United States and can alleviate or decrease the incidence of morbidity and mortality from electrolyte imbalance and uremia; however, it is not without complications. A major complication in the end stage renal disease population is lower extremity amputation from vascular complications and nonhealing wounds. According to O'Hare, Feinglass et al.(2011) the incidence of nontraumatic lower extremity amputation among the end stage renal disease (ESRD) population in the United States is ten times higher when compared to the general public.

The most common vascular complication among end stage renal disease patients with peripheral artery occlusive disease, after transplant, is amputation (O'Hare et al., 2001). The Dialysis Outcomes and Practice Patterns Study (DOPPS) indicate amputation prevalence to be 6% with an incidence of 2.0 events/100 patient years at risk for hemodialysis patients; diabetic patients exhibited a more than 9 times greater incidence of new amputation (Combe et al., 2009). Diabetic dialysis patients reflect a relative risk of mortality after amputation of 1.54 with a mean survival of 2.0 versus 3.8 years for nondiabetics on dialysis (Combe et al., 2009). This can be attributed to many factors including the large number of diabetics requiring renal replacement therapy, the increased age in which dialysis is being initiated, increased inflammation from numerous sources as reflected by elevated C reactive protein levels, placement and maintenance of a hemodialysis access, and factors related to metabolic bone disease.

Significance of the Problem

Peripheral artery disease is a common condition in the chronic kidney disease (CKD) population leading to an increased prevalence of cardiovascular disease (primary cause of morbidity and mortality) (Combe et al., 2009). The overall incidence of peripheral vascular disease (PVD) in hemodialysis patients is 25-28 percent (Plantigna et al., 2009) representing a quarter of the ESRD population. Unfortunately, the alarming number of ESRD patients with vascular disorders not only increases the potential for cardiovascular events but also for amputation. Research from a cross sectional study performed by Ndip, Rutter et al. (2010) on diabetic patients with stage 4 and 5 kidney disease reflects the incidence of foot ulcerations increases with decreasing glomerular filtration rate. Compared to those not on dialysis, research shows that patients on dialysis

experience more foot deformities, a five times increase in foot ulcerations, and a 2 times increase in prior amputation, diabetic neuropathy, and PVD (Ndip, Rutter et al., 2010).

Data gleaned from the 1996-2004 Dialysis Outcomes and Practice Patterns Study (DOPPS), indicates the cause of the majority of 29, 838 hemodialysis patient amputations is due to peripheral vascular disease. Combe et al., (2009) work reflects, 75% of prior amputations performed on chronic kidney disease patients can be attributed to peripheral vascular disease (PVD), 14.6% for other reasons, and 10.5% to an amputation due to PVD and reasons other than PVD. Of the patients enrolled in the DOPPS study, with a prior amputation, 91% had a diagnosis of PVD (Combe et al., 2009).

Background of Kidney Failure and ESRD

According to the Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines from the National Kidney Foundation [NKF] (2002), renal failure is a glomerular filtration rate (GFR) $<15\text{mL/min/1.73m}^2$ or the need to initiate renal replacement therapy due to uremic symptoms or the increase possibility of morbidity and mortality. However, not all individuals with a GFR $<15\text{mL/min/1.73m}^2$ will initiate dialysis as reflected by individuals with a functioning kidney transplant.

There are currently five stages of chronic kidney disease recognized by KDOQI (2002) guidelines. Stage 1 demonstrates kidney damage with a normal or increased glomerular filtration rate (GFR) ≥ 90 (for example proteinuria). Stage 2 demonstrates a mild decrease in GFR 60-89. Moderate kidney damage is noted in stage 3 with a GFR 30-59. Stage 4 demonstrates a severe decrease in GFR 15-29 and the patient may reflect complications with anemia and the beginnings of metabolic bone disease. A GFR ≤ 15

is noted as stage 5 kidney disease and the majority of patients will be on dialysis or anticipating initiation in the near future.

Management of ESRD

Management of kidney failure/ESRD is treated by renal replacement therapy or through a kidney transplant. Dialysis is performed on individuals with acute kidney failure requiring dialytic support or those with chronic renal failure in end stage renal disease. The process removes waste products, electrolytes, and fluid from the blood that are normally eliminated via the kidneys. There are two types of dialysis, hemodialysis and peritoneal dialysis.

Amputation in ESRD

Hemodialysis patients exhibit numerous co-morbid conditions decreasing their life expectancy when compared to the national average. According to Goodkin et al. (2003) the list of primary co-morbid conditions reflected through DOPPS research includes cardiac conditions such as coronary artery disease, congestive heart failure, cardiomegaly, and left ventricular hypertrophy. Diseases, non-cardiac in origin, include peripheral vascular disease, diabetes, dyspnea, smoking, cancer, hepatitis B, hepatitis C, chronic cellulitis, and so forth.

The United States Renal Data System (2011), reports life expectancy of a dialysis patient between the ages of 40 and 44 years to be approximately 8 years and for patients 60 to 65 years of age the average is 4.5 years (Mailloux & Henrich, 2012).

Unfortunately, life expectancy decreases further should a lower extremity amputation become necessary. In a study conducted by Eggers, Gohdes, and Pugh (1999), data were gathered using hospital ICD-9 codes from 1991-1994. The information provides post operative survival rates for renal replacement therapy patients listed in the Health Care

Financing Administrations' ESRD program management and information system (PMMIS). The 30 day postoperative survival rate following amputation for ESRD patients was 88.9%, 49.3% at one year, followed by 32.7% at two years postoperative.

According to the National Institutes of Health (NIH) (2004), the number of ESRD patients that underwent an amputation from 1996-2001 was 49,708. Of this number only 33.7% were living 730 days following surgery or approximately 16,751 patients. Of the current patients on dialysis in the United States it is estimated that 18, 000 hemodialysis patients will undergo an amputation resulting in an increased mortality, lack of productivity, and increased depressive disorder diagnosis.

Furthermore, data from the US Renal Data System (USRDS) displays postoperative mortality rates among dialysis patients undergoing revascularization procedures as 12.6% and 7.5% for bypass and angioplasty respectively (Plantigna et al., 2009). Information gained from the Department of Veterans Affairs' National Surgical Quality Improvement Program (n=16,994) reflects postoperative mortality at 16% for dialysis patients compared to 6% for individuals with normal or mild renal impairment (O'Hare et al., 2004). To further bolster these findings, the Choices for Healthy Outcomes in Caring for ESRD (CHOICE) study (n=1,041) reflects 21% of dialysis patients in the study experienced a PVD related procedure after the initiation of dialysis. A three year follow up of the same patients reflects 70% required amputation and over 25% underwent revascularization. A total of 60.7% patients experienced at least two PVD related procedures during follow-up with greater than 30% requiring three procedures (Plantigna et al., 2009).

Background ESRD and Factors Influencing Vascular Complications

Nearly 44% of all new dialysis patients in the United States initiate renal replacement therapy as a result of diabetic nephropathy (Mahnensmith, Zorzanello, Hsu, and Williams, 2010). According to Ishimura et al. (2007) diabetic patients begin to experience vascular calcification prior to the initiation of dialysis. The calcification is associated with hyperglycemia and other metabolic complications and leads to increased progression of diabetic nephropathy.

Annually, 50-80% of the lower extremity amputations in the United States can be directly attributed to diabetes (Locking-Cusolito et al., 2005). Among individuals with diabetes, the prevalence of peripheral artery occlusive disease is four to seven times greater than the general public estimated at 3.5-23% (Locking-Cusolito et al., (2005). Unfortunately, the number of individuals with diabetes is expected to reach pandemic proportion with an increase of 165% by 2050 (Boyle et al., 2001). The upsurge reflects an anticipated escalation from a diabetic population of 11 million (prevalence 4.0%) in 2000 to a diabetic population of 29 million (prevalence 7.2%) by 2050 (Boyle et al., 2001). The massive increase in the number of diabetics will create a subsequent rise in hemodialysis patients and reflect a growth in vascular complications and amputations. Evidence gleaned from a small study by Beckert, Sunderman, Wolf, Konigsrainer, and Coerper (2009) suggests hemodialysis may actually increase the risk of amputation in diabetics. Research demonstrates changes in “cutaneous microcirculation” (Beckert et al., 2009, p. 89) and a decrease in blood flow in patients with diabetes undergoing hemodialysis leading to limb complications (Beckert et al., 2009). The research further supports information obtained from the Medicare database, reflecting diabetics on

hemodialysis are 10 times more likely to require an amputation when compared to diabetics not requiring renal replacement therapy (Combe et al., 2009).

Broersma (2004) states the mortality rate after amputation in patients with diabetes is 11-41% at 1 year, 20-50% at three years, and 39-68% at 5 years. Lower extremity amputations for dialysis patients generally result in the loss of a toe, foot, or limb. Unfortunately, difficulties leading to the amputation generally increase complications due to impaired mobility (Eggers et al., 1999).

Renal replacement therapy patients are increasing in age due to prolonged life expectancies and the graying of the baby boomer generation. Unfortunately, age also plays a key role in vascular complications. According to the USRDS (2011), dialysis patients age 65 and older exhibit a two fold increase in mortality compared to the general population that have disease complications including diabetes, cancer, congestive heart failure, cerebral vascular accident (CVA), transient ischemic attack (TIA), or acute myocardial infarction (AMI).

Razeghi, Omati, Maziar, Khashayar and Mahdavi-Mazdeh (2008), view chronic inflammation as a primary factor in vascular disease notably cardiovascular and atherosclerotic changes. Between 30 and 50% of hemodialysis patients display increased serum inflammatory markers reflected by elevated C-reactive protein (CRP) levels (aids in predicting short term mortality) and increase albumin (albumin levels increase with chronic inflammation). Regrettably, there are a number of factors that occur during dialysis that can increase inflammation. Many of these factors are non-modifiable such as access cannulation and iron administration.

The hemodialysis population endures cannulation of their dialysis access three days weekly (or as prescribed for home hemodialysis usually 6-7 times weekly) causing increased incidence of inflammation at the cannulation site. Should a fistula or graft become nonfunctional a temporary catheter may be placed creating a means for hemodialysis; however, trauma during placement of the catheter and repeated irritation of the skin from catheter movement increases inflammatory markers.

A second cause of elevated inflammatory levels in the ESRD population is the regular administration of intravenous iron. According to Jofre et al (2006), intravenous iron is hypothesized to cause increased irritation and inflammation. This results in an increase in advanced oxidation protein product levels, which are related to CRP levels, and in common carotid artery intima-media thickness (Jofre et al., 2006).

Another potential contributor to vascular complications in the renal replacement population is placement of a hemodialysis access. Hemodialysis requires the use of an arteriovenous fistula, arteriovenous graft, or tunneled catheter for blood removal, cleansing, and replacement. Upper extremity accesses are generally placed due to comfort to the patient, ability for quick utilization by the staff, and access longevity.

Access placement can also lead to limb ischemia due to redirection of blood flow referred to as steal syndrome. According to Mickley (2008), access placement in the lower limbs can create a 16%-36% incidence of steal syndrome. Access-related steal syndrome progression can lead to resting pain and eventually necrosis. Severe incidences of steal syndrome, left uncorrected, can result in amputation. In a study performed by Miller, Robbin, Barker, and Allon (2003) data was collected on 409 grafts placed over

3.5 years at a single location. Of the 409 grafts placed 63 were thigh grafts. The end result reflects technical failure for thigh grafts as twice as high as upper extremity grafts.

Perhaps the most common and somewhat modifiable cause of vascular complication in the ESRD population is calcification due to metabolic bone disease. Metabolic bone disease is common in renal replacement therapy patients due to hyperphosphatemia, hypocalcemia, decreased vitamin D, and hyperparathyroidism. The combination of these factors can create the basis for adynamic bone disease and vascular calcification. The Choices for Healthy Outcomes in Caring for ESRD (CHOICE) study reiterates elevation in serum phosphate as directly associated with vascular calcification and cardiovascular outcomes. Hyperphosphatemia is common in PVD and may be associated with peripheral artery stiffness (and thus progression of PVD) in patients with kidney disease and diabetes (Plantigna et al., 2009). Altered levels of serum calcium, phosphorus, and calcium-phosphorus product influence the occurrence and rate of soft tissue and vascular calcification (mineralization). The altered mineralization may contribute to vascular occlusive disease in the coronary, peripheral, and cerebral circulations (Young et al., 2005).

Metabolic bone disease can begin prior to dialysis during the last stages of chronic kidney disease. Lab values reflect alterations in phosphorus, calcium, vitamin D, and parathyroid levels. As kidney disease progresses systems that are part of the body's compensatory mechanism for homeostasis overcompensate creating alterations in management and low bone turnover. Adynamic bone disease incorporates hypercalcemia and the addition of large levels of vitamin D causing suppression of the parathyroid. Current research related to the administration of calcium binders and vitamin D, which

has been a mainstay in hemodialysis, indicated that they may be actually contributing to this over suppression resulting in vascular calcification and increased mortality.

According to Martin and Gonzalez (2007), current evidence suggests that vascular calcification is an ongoing process similar to skeletal mineralization. Studies suggest that the normal vessel wall expresses proteins to inhibit calcification and circulating proteins are produced to inhibit soft tissue calcification. According to Martin and Gonzalez (2007), alterations in the proteins may cause changes to smooth muscle cells of vascular tissue causing osteochondrocytic like cells that increase calcification. Both clinical and basic research findings indicate an inverse relationship between bone mineralization and vascular calcification (Martin & Gonzalez, 2007) thus leading to increased risk factors for individuals undergoing renal replacement therapy.

Phosphate retention and hyperphosphatemia are extremely common in patients with ESRD. In the United States, serum phosphorus concentrations are elevated in >70% of patients who are treated with regular hemodialysis, despite the use of phosphate binding medications. A primary metabolic parameter to control is the amount of phosphorus consumed in the patient's diet and the type/amount of phosphorus binders prescribed.

Controlling hyperphosphatemia also enlists the assistance of the dialysis patient. They must follow a strict diet (phosphorus is a common preservative in numerous food items and beverages) by limiting or abstaining from foods that have a high phosphorus content. Phosphorus binders must be consumed with each meal (the number of binders is dependent on phosphorus, calcium, parathyroid levels and the prescriber) and snacks making compliance an issue. Nichols-English and Poirier (2000) report individuals do not

take medications as prescribed at least 13% to 93% of the time (average 40%).

Medication adherence decreases with the number of medications, number of chronic conditions, and the number of times the medication is prescribed daily. Phosphorus binders are consumed with each meal and most snacks for an average of four times daily. According to research by Brown and Bussell (2010), adherence to medication is approximately 79% ($\pm 14\%$) when dosing is limited to one time daily and compliance decreases to 51% ($\pm 20\%$) when medication is dosed four times daily. Compliance levels decrease by another 10% with each additional medication dosage.

Purpose

Due to the increased prevalence of vascular complications in the dialysis population, it is critical to have a protocol for early assessment and intervention to prevent limb loss and mortality. The dialysis population requires vigilant monitoring for early detection and intervention of vascular complications, however, the means to determine which patients require vascular testing is not currently required by the National Kidney Foundation. Although the literature reflects prevalent factors that lead to cardiovascular disease and loss of limb in the ESRD population, this project will be limited to the examination of the lower extremities of hemodialysis patients with diagnosed diabetes or over the age of 65 years at Upstate Dialysis in Greenville, SC.

The purpose of this project is to translate change in the practice setting by implementing an evidence based approach to improve early recognition and intervention of vascular complications and sequale. The focus is to integrate a lower extremity assessment tool in a renal dialysis unit.

PICO Question

The PICO question for this project: Will the use of a dedicated lower extremity assessment tool performed on adult hemodialysis patients over 65 years of age or diabetic increase the likelihood of early detection and intervention for potential vascular complications? Early detection will be measured by an abnormal monofilament test, discoloration or pain of the extremity or impairment of the skin integrity. Intervention will be measured by the number of wound care/vascular /podiatry referrals made following initiation of the lower extremity assessment tool, the recurrent monthly use of the tool, correct charting of normal findings, abnormalities that are stable, and abnormalities that meet referral guidelines. As reflected in table 1.1, outcome comparisons will be made on the same hemodialysis patients before and after initiation of a dedicated lower extremity assessment tool. PICO definitions and descriptions were provided to each professional nurse as noted below and in table A.1 in the Appendix.

Table 1.1

Evidence Based Practice Clinical Question

Patient Population	Intervention	Comparison Intervention	Outcome
Hemodialysis patients that are over the age of 65 years or diabetic at Upstate Dialysis	Utilization of a dedicated lower extremity assessment tool	Absence of lower extremity assessment	Early referral and intervention for potential vascular complications

PICO Definitions and Descriptions

- Abnormal- not normal or average, deviating from a standard (Collins English Dictionary) abnormal for this study will include absence/decreased dorsalis pedis pulse, irregular monofilament test, alteration in skin integrity, alteration in toe nails

- Abnormal/stable- not normal or average, deviating from a standard (Collins English Dictionary) but considered unchanged
- Adult patients over 65 years of age-individuals requiring dialysis born after this date in 1947
- Chronic kidney disease-“individuals with GFR <60 mL/min/1.73 m² for ≥ 3 months” (National Kidney Foundation, 2002)
- ESRD- acronym for end stage renal disease; “is an administrative term in the United States, based on the conditions for payment for health care by the Medicare ESRD Program, specifically the level of GFR and the occurrence of signs and symptoms of kidney failure necessitating initiation of treatment by replacement therapy. ESRD includes patients treated by dialysis or transplantation, irrespective of the level of GFR” (National Kidney Foundation, 2002).
- Lower extremity- from the hip to the toes (includes the hip, knee, ankle joints, bones of the thigh, leg, and foot) (Cluett, 2009)
- Normal- not abnormal; conforming to the expected (Collins English Dictionary)
- Renal replacement therapy- “procedures which temporarily or permanently remedy insufficient cleansing of body fluids by the kidneys” (Reference.MD)
- Vascular complications-difficulties with the vessels or ducts resulting in blockage, atherosclerosis, or the need for surgery to repair blood flow

Framework/Model of Research Utilization

Hemodialysis professional nurses practice in a high acuity environment requiring ongoing modifications to protocols, medications, and patient acuity. Professional nurses

must quickly adapt to changes in their environment, yet maintain a sense of normality and confidence. Therefore, Kurt Lewin's change model can be incorporated into the dialysis setting. Kurt Lewin encouraged change through restructuring to create new insight. His approach included field theory, group dynamics, action research, and a three step model of change. This project used a three step model composed of unfreezing, change, and refreezing (Burnes, 2004).

The initial stage in Lewin's theory is unfreezing. Unfreezing is necessary to overcome resistance and create conformity, limiting opposing thoughts or ideas that may hinder advancement (Nursing Theories, 2011). For Lewin, human behavior was based on apparent balance. He believed old behavior could not be eliminated (unfrozen) until new behavior is adopted and equilibrium is reached. Lewin believed change incorporates unfreezing through motivation and education (Burnes, 2004). The initiation of a lower extremity assessment tool at Upstate Dialysis will require unfreezing through staff education. It will require open lines of communication, staff participation, and ownership from key nurses for a smooth transition.

The second stage in Lewin's theory is change or transition. This stage requires the development of new behaviors, attitudes, and incorporation of a new mindset. It will include "a change in thought, feeling, behavior, or all three" (Nursing Theories, 2011). The change will require the nurses to move away from their level of comfort and embrace new education and a protocol. As with any transition there may be a certain degrees of confusion or uneasiness. This can be limited or dissipated by reminders and assurance. Change will include initiating a lower extremity tool through nursing education. The

nurses will be required to learn, incorporate, and follow a prewritten lower extremity guide for dialysis patients over 65 years of age or diabetic.

Lewin's third step of refreezing stabilizes the group and prevents regression to previous habits. Lewin believed change as a group aided in creating permanent change as individual behavior is more likely to regress to previous levels (Burnes, 2004). This stage includes adaptation of the change or regression to prior knowledge. Stage three determines if the change is successful and is incorporated into the daily work routine. If the change is not permanent and a transition is still warranted the process will need to be reinitiated with unfreezing.

In this stage the lower extremity tool should be second nature to the staff. There should be a level of comfort and the nurses should be empowered with the ability to follow the tool and make informed decisions. Any changes or emergent matters should be brought to the attention of the medical staff, APRNS, professional nurses. Stable individuals may be discussed at the monthly continuous quality improvement (CQI) meetings.

Summary

Renal replacement therapy patients are at an increased risk for death from a vascular incident when compared to the national average. This increase is compounded by the number of risk factors that cannot be modified such as the presence of diabetes, age, inflammation, access placement, and to an extent metabolic bone disease. It is not prudent; however, to perform a carotid ultrasound, lower extremity doppler, cardiac catheterization, and so forth on a monthly or even yearly basis due to cost, lack of resources, and the inability of many patients to undergo evasive procedures. Therefore, a

quick, simple, noninvasive guide is necessary to pinpoint individuals that are at increased risk of a vascular incident. A lower extremity assessment tool will not provide the same results as an arteriogram or a CT scan; however, it will provide information as to the health of the vascular system and aide in making referrals for early detection.

Inevitably, with the large number of hemodialysis patients that will require vascular intervention from diabetes or advanced age factors there will be an increase in mortality risk. Long term prognosis following PVD related procedures is not favorable for ESRD patients who undergo lower extremity amputations or bypass following the initiation of dialysis. According to the Plantigna et.al (2009), postoperatively dialysis patients experience a 4 time increase risk of mortality, 3-5 increase risk for cardiac arrest, and twice the risk for sepsis when compared to individuals not requiring renal replacement. Of the dialysis patients that required amputation there was a 3.4 increased risk for postoperative mortality. Results from the CHOICE study confirm poor postoperative outcomes following PVD related procedures in dialysis patients. The results are further extended over the course of dialysis to show that prognosis does not substantially improve over time after such procedures. Therefore, possible preventative strategies are of utmost importance.

CHAPTER II

ANALYSIS OF THE LITERATURE

The analysis of the literature is an important element in an evidence-based approach to this project. Chapter two describes each step in the literature search process. Each step in the literature analysis must be scrutinized allowing for a summary of the main points and creating documentation that may be followed in future research.

Search Process

An initial literature review was performed using CINAHL with full text, Gale, the Cochrane Library, Collegiate Discus (EBSCO), the Joanna Briggs library, Essential Evidence Plus, Medline Ovid, and references from articles determined to be within the scope of practice of this paper. Search terms include dialysis, wound, and prevention, amputation, ESRD, risk factors for amputation. Inclusion criteria incorporated full peer reviewed articles available in English, from 1990 to the present, and involving information on human subjects. As noted in table 2.1, the search process yielded over 1,766 articles; however, many of the articles mentioned ESRD as a comorbid condition and did not provide information on lower extremity assessments. The articles were evaluated by title, a number were excluded due to the title listing diabetic foot assessment or infection as the primary focus. The abstracts of the remaining articles were evaluated to determine if they met the criteria for this quality improvement project decreasing the number of articles to 64 with an additional 11 articles obtained through bibliography review.

As the scope of the needs based assessment tool began to form it was evident that multiple literature reviews would become necessary to gain the scope of each complication factor including diabetes, advanced age, inflammation, access placement, and metabolic bone disease. Each of the above elements was investigated in Google search engine and Medline (diabetes and ESRD and vascular complications and PVD, age and ESRD and vascular complications and PVD and so forth). The amount of information was limited; however, material was obtained through government collecting houses or databases such as the USRDS and NIH.

Table 2.1

Results of the Search Process with Key Words

Data Base	Key Words	Results
CINAHL with full text	1. dialysis, wound, and prevention	17
	2. dialysis and peripheral wound	9
	3. dialysis and lower extremity	42
Gale	1. dialysis and peripheral wound	0
	2. dialysis and vascular	2
Cochrane Library	1. dialysis and wound	1
	2. dialysis and lower extremity	1
Collegiate Discus (EBSCO)	1. dialysis and wound	61
	2. dialysis and lower extremity	33
Joanna Briggs library	1. dialysis and wound and prevention	0
Essential Evidence Plus	1. dialysis and lower extremity	17
	2. dialysis and peripheral wound	2
Medline Ovid	1. dialysis and wound and prevention (limited to English, human, and	1766

	peer reviewed)	
Bibliography from useful articles	Information gathered from the bibliography of cited articles using the title of the article and author	13

Practice guidelines from the systematic review were scrutinized and rated using criteria from the Scottish Intercollegiate Guidelines Network (SIGN) as noted in table 2.2. SIGN (2001) is a cooperation of resources that utilizes systematic reviews, supporting evidence, and national research to define current evidence based practice. There primary focus is reduction in variation of healthcare in Scotland and development of a common pool of recommendations backed by evidence from a wide variety medical specialties. The SIGN system encourages cooperation between developers, researchers, and individuals synthesizing evidence based information allowing for a wide variety of involvement and recommendations. Due to the nature of collection techniques the results and recommendations are less likely to contain bias.

Table 2.2 SIGN: Key to Evidence Statements and Grades of Recommendations

Levels of Evidence

Rating	Criteria
1++	High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews, or RCTs with a high risk of bias
2++	High quality systematic reviews of case control or cohort studies High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2+	Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

- 2- Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
 - 3 Non-analytic studies, case reports, case series
 - 4 Expert opinion
-
- Scottish Intercollegiate Guidelines Network, 2010

Statistical Methods

The statistical methods used in information gathering included ANOVA, *t* testing, Mann-Whitney *U* test, Pearson χ^2 and Fisher exact tests. The type of data to be analyzed determined the statistical methods used. The findings from the research varied depending on sample size, culture, age, and so forth. What remained consistent throughout the literature is the overwhelming mortality rate in patients undergoing hemodialysis with PVD and amputations.

Analysis of the Literature

A review of the literature revealed a need for early wound intervention and prevention of amputation in the ESRD population; however, the information available was both limited and dated (table A.3 in the Appendix). Much of the literature focused on diabetic wound assessments, prevention, and management but did not address hemodialysis issues such as access placement or steal syndrome. The information below is synthesized based each on type of study. A SIGN rating is assigned to each study discussed.

Case Control Study

Lavin-Gómez et al. (2011) conducted a case control study comparing serum and ethylenediaminetetraacetic acid (EDTA) plasma from 69 healthy individuals in the

general public and 70 patients with differing stages of chronic kidney disease. Results showed that severe chronic kidney disease incorporates a low level of inflammation as determined by an elevated CRP and serum component of amyloid A when compared to the general population. Plasma pentraxin 3 and procalcitonin only increased in end stage renal disease patients. The increased risk factors encourage a recommendation of aggressive treatment in CKD patients with increased inflammation to prevent cardiovascular complications. The case control study was given a SIGN value of 2++. The level of bias was low and there was a high level of probability that the results were causal.

The case control study performed by Ndip et al. (2010) attempted to determine if dialysis was an independent risk factor for foot ulceration among diabetics with stage 4 or 5 kidney disease. Data were collected from the patient and the medical chart. The research reflected a higher incidence of diabetic peripheral neuropathy, peripheral vascular disease, prevalent foot ulcers, and a fivefold increase in foot ulcerations for diabetics on dialysis when compared to those not undergoing renal replacement therapy. A SIGN rating of 2++ was given to the case control study. It was well performed with a low level of bias.

Cohort Study

Beckert et al. (2009) performed a small research study to examine cutaneous microcirculation in the dorsum of the foot during and following hemodialysis to compare the events of diabetic and non-diabetic patients. The sample size included 14 individuals that were age matched (7 diabetic and 7 non-diabetic). Differences between the two groups were calculated by Mann-Whitney *U* test and ANOVA following post hoc testing.

The resulting information discovered an increase in blood flow of the non-diabetic hemodialysis patients when compared to the diabetic hemodialysis patient.

Analysis performed by Miller et al. (2003) illustrates the difficulties in maintaining a lower extremity arteriovenous graft. The study followed individuals that underwent the creation of a graft at the University of Alabama Birmingham over a 3.5 year period. Of the 409 grafts placed, 63 were thigh grafts. The technical failure rate was approximately twice as high for the thigh grafts compared to those created in the upper extremity, however permanent failure rate was similar. The median time for permanent loss of the thigh graft was 14.8 months compared to the upper extremity graft at 20.8 months. Research by Miller et al. (2003) is given a sign of 2+. It is well performed and documented using a large population over a specified time frame. The research is not randomized due to surgery requirements being varied among the groups.

Statistical information was gleaned from a study performed by O'Hare et al. (2004) examining the postoperative mortality of patients with renal insufficiency following nontraumatic amputation of a lower extremity. The study utilized data from 16,944 patients, from January 1, 1994 to September 30, 2001, undergoing their first amputation as recorded by the Department of Veterans Affairs' National Surgical Quality Improvement Program (NSQIP). The review provided information as to the increased risk that individuals with renal insufficiency face when compared to those without renal complications. The end point of the study reflects 52% of the individuals that died postoperatively had at least moderate renal insufficiency. This is compared with 6% postoperative deaths with normal or mild renal insufficiency. Of these statistics 16% of the deaths were individuals on dialysis. The article was given a SIGN value of 2++. The

information was gathered from patients across the country through the utilization of a database maintained by the Veterans Association. The only potential for bias was the nonuse of those seeking assistance in a hospital setting not associated with a VA medical center. The information, although unique and promising, was assigned a SIGN grade of 2- due to the reliability of the small sample size. It is noted that the decrease in blood flow could be related to differing degrees of calcification.

A cohort study was performed by Zimmermann, Herrlinger, Pruy, Metzger, and Wanner (1998) measuring the relationship of inflammatory markers and mortality. The results suggest that many hemodialysis patients are at an increased risk of cardiovascular incidents. It is believed to be an acute phase reaction (unidentified mechanism) and provides recommendation for inflammation treatment. The cohort study was well performed and follow up was provided at 12 and 24 months. A SIGN value of 2++ was noted. Information gathered again revealed the need to monitor CRP levels in dialysis patients.

International countries with large populations of dialysis patients were included in the Dialysis Outcomes and Practice Patterns Study (DOPPS). Information obtained by Young et al. (2005) reports a study sample that included 17,236 randomized participants with data obtained from medical records using a standardized questionnaire. Follow up data was collected every 4 months. The primary outcome included cardiovascular mortality, parathyroidectomy, and total mortality with predictor variables - patient baseline characteristics, patient baseline mineral metabolism labs, and modifiable practice patterns related to mineral metabolism. A sign rating of 2++ was given to the

study due to the low risk of bias and repeated record review. The sample size included a large number of individuals from several international countries.

A prospective observational study was also performed on the DOPPS data by Combe et al. (2009) describing the incidence of amputation following initiation of hemodialysis. Information was gathered using logistic regression and Cox models. Amputation was noted as a common occurrence with increased risk in diabetics and associated with traditional cardiovascular risks and factors linked to kidney disease. This article was also given a SIGN value of 2++. The information used in the study reflects a low level of bias. According to Combe et al. (2009) the single limitation was data collected did not differentiate type of amputation.

Controlled Clinical Trial

Information obtained by the randomized controlled clinical trial performed by Locking-Cusolito et al., (2005) exhibited the use of a lower extremity assessment tool that required 20 minutes by a trained nurse practitioner to perform. It provided much needed data as to risk factors including dry skin, cracked fissured skin, claw toes, and so forth. Of the 232 hemodialysis patients sampled there were 708 physical risks identified. Also noted were self care deficits: only 2.6% of the patients reported performing daily foot care including inspections, cleaning, moisturizing, and nail care (trim/file). Unfortunately, a number of the individuals were not physically capable of completing the home assessments due to vision issues, complications with dexterity, flexibility, and not having adequate assistance at home.

The data provided a firm basis for the need for lower extremity assessments in the dialysis unit. Unfortunately, it was only performed as a onetime assessment so further

data could not be analyzed. Limitations to the study include demographics as the dialysis unit was located in a large, urban, academic center with a number of Canadian patients. Also, there were a number of individuals providing data collection which may cause differences in interpretation and inter rater reliability. The study was given a SIGN rating of 1+ due to its scholarly form and data collection.

Cross Sectional Study

Guérin et al. (2000) performed a cross sectional study in which 120 stable end stage renal disease patients were evaluated to determine the influence of arterial calcifications on arterial stiffness. Each patient underwent B-mode ultrasound of the common carotid artery, aorta, and femoral arteries to determine the presence of vascular calcifications, elastic incremental modulus, and common carotid artery ability to stretch/distend. The results illustrate a correlation between arterial stiffness, aortic stiffness and vascular calcifications. The extent of the calcification influenced ventricular afterload and inversely influenced stroke volume.

Razeghi, Omati, Maziar, Khashayar, and Mahdavi-Mazdeh (2008) conducted a cross sectional analysis of 114 hemodialysis patients in two dialysis units. Information gathered suggests a relationship between inflammation and nutrition. Recommendations include monitoring of CRP levels for inflammation. A SIGN value of 2+. The data included lab values displaying increased levels of CRP in relation to nutrition. However, there was not a discussion of literature review or history leading up to the research. It appears to be based on expert opinion of the researchers and common knowledge from the recommended audience.

Expert Opinion

William Goodman is one of the top advisors for Amgen on hyperparathyroidism secondary to renal insufficiency. His research concluded that new strategies need to be implemented to control hyperparathyroidism and hyperphosphatemia. A large amount of his research has been with the use of calcimimetic agents and inhibition of parathyroid hormone release by activating calcium receptors in the gland itself. SIGN value of 4 was provided due to the article being an expert opinion.

Norma Gomez provided her expert opinion on end stage renal disease wound care. She described risk factors, healing process, how to perform an accurate assessment, and wound care strategies. It was given a SIGN value of 4 for an expert opinion.

Expert opinion concerning inflammation in the hemodialysis patient was provided by Jofré et al. (2006). Information took into account inflammatory markers, existing comorbidities, infection, oxidative stress, and so forth. The article provided information on vascular calcification and inflammation due to hemodialysis techniques and increased mortality rates for hemodialysis patients with inflammatory syndrome. Recommendations listed prevention and treatment of inflammatory syndrome. A SIGN level of 4 was assigned to this article. Information was gathered by the authors and opinion as to limiting modifiable inflammation was identification of markers was presented.

Systematic Review

Broersma (2004) published a systematic review illustrating an increased need for vigilance in amputation prevention in the chronic kidney disease patients in relation to those with diabetes. The article provided statistics, risk factors, and guidelines for a diabetic foot exam and incorporated complications including neuropathy, charcot

deformity, increased plantar pressure, and so forth. The article was given a SIGN value of 1++. The information was a systematic review published by the Nephrology Nursing Journal for continuing education credit. Unfortunately, the article did not provided information listing the number of articles reviewed or how the articles were obtained.

A review was performed by Brown and Bussell (2011) using MEDLINE to determine the rate of medication adherence. Research found that approximately 50% of patients do not adhere to their prescribed medication regimen and the identification of solutions was multifactorial including the patient, provider, and the process. A SIGN value of 1+ was given to the review performed by Brown and Bussell (2011). There is a low level of bias and information was gathered through a database literature search and citations from retrieved articles.

Eggers, Gohdes and Pugh (1998) calculated the number of ESRD patients that underwent lower extremity amputations between 1991 and 1994 covered by Medicare. The information was obtained through the collection of hospital ICD-9 codes from the Health Care Financing Administration's ESRD management and medical information system. Peripheral vascular disease and diabetes were factors included in their research. Conclusions were made with the information obtained and research from other sources. Due to the gathering of information using ICD-9 codes the level of bias should be minimal; however, the data gathered is limited to only individuals on Medicare. The SIGN value 1++ was applied.

A systematic review performed by Ishimura et al. (2008), demonstrates the increased risks of vascular calcification for patients on dialysis with and without diabetes. The main points of the article describe risk factors for vascular calcification, high

phosphorus levels as a pronounced risk factor for non-diabetic ESRD patients, factors for calcification in diabetic ESRD patients, and reasons for tight glycemic control in diabetic ESRD patients. A SIGN value of 2++ was given due to the data collection provided. The data was combined with prior research by the authors to provide added support to their conclusion that diabetics form calcifications before initiation of dialysis due to poor glycemic control; however, non-diabetic ESRD patients are at an increased for calcifications from hyperphosphatemia (metabolic bone disease).

Martin and González (2007) created a systematic review on metabolic bone disease including abnormalities in vitamin D, parathyroid hormone, and calcium focusing on pathogenesis and management. A SIGN value of 1++ was provided as the information exhibited a low level of bias and included factual material in a concise manner. The research provided an accurate assessment of hyperparathyroidism in chronic kidney disease and the cascade of metabolic factors leading to adynamic bone disease and osteitis fibrosa.

Nichols-English and Poirier (2000) provide a study of medication adherence and reasons why patients do not comply with medical management. Methods are provided to assess adherence, create medical management, and increase comfort zone for those with multiple medications. The article is written from a pharmacist perspective but provides valuable insight as to why medications are not always taken as prescribed. The article was given a SIGN value of 1+ with a low level of bias.

Summary

The literature review for this project revealed as much as 50% to 85% of lower extremity amputations associated with diabetes can be avoided or delayed through

educational and treatment programs (Locking-Cusolito et al., 2005). The importance of prevention is highlighted by increased mortality following amputation in the dialysis population. Methods to preventing amputation and decreasing ulceration include patient/provider education and regular foot examinations. A recent study indicates foot programs can be implemented as a preventive measure in the hemodialysis unit (Broersma, 2004). However, despite the increased risk and potential loss to amputation limited efforts are made to provide preventive foot assessments or monitor for future complications. Broersma (2004) reiterates that preventive foot care, early detection, and follow up care are not routine in hemodialysis units despite frequent contact with nephrology nurses and ample opportunity for assessment, education, and early intervention. This lack of monitoring lends to a lost opportunity in reducing the threat of amputation.

The CDC (2011), lists comprehensive foot care programs, i.e., that include risk assessment, foot-care education, preventive therapy, treatment of foot problems, and referral to a specialist as a way to reduce amputation rates by 45% to 85%. At this time, the National Kidney Foundation does not require a comprehensive foot care program to be performed on patients undergoing renal replacement therapy.

In addition, there is an absence of national guidelines addressing lower extremity evaluations in the hemodialysis patient despite statistics that clearly reflect a need for ongoing assessment. The best initial practice for the ESRD population would be to create a lower extremity assessment algorithm for use in the hemodialysis units with information gleaned from current best practice in diabetes and peripheral vascular assessment lending to new protocols and policies.

CHAPTER III

METHODS

The quality improvement project was guided by evidence provided by the literature search and methods based on Lewin's Change Theory. The Change Theory provided a guideline to decrease barriers while instilling confidence in the new algorithm. The design of the lower extremity algorithm included information from best practice studies and utilization of professional nurses educated in the use of the algorithm.

A primary reason for this lower extremity assessment algorithm project for hemodialysis patients was the number of amputations noted during weekly dialysis rounds. Due to the many co-morbid conditions in the ESRD population, including loss of vision and peripheral neuropathy, it is challenging for the patients to perform a foot assessment at home. This lack of ability leads to increased incidence of wounds, toe nail complications, and rashes creating potential sources of infection.

Design

A review of the literature, in combination with complications noted in the dialysis units, revealed a need in the ESRD population for lower extremity assessments. The literature, although limited and dated, plainly states foot assessments should be performed due to increased mortality following amputation and revascularization in this population. The literature review revealed an increasing number of diabetics and elderly currently receiving hemodialysis. Due to the vulnerability of this subset of the ESRD

population to skin alterations and increased vision difficulties they were chosen for this project.

Setting

This quality improvement project took place at Upstate Dialysis in Greenville, SC. The unit census at the time of the quality improvement project included 148 patients (80% hemodialysis and 20% peritoneal dialysis). Of these patients 6% were type 1 diabetics, 42% type 2 diabetics, and 42% of patients were over the age of 65 years. The dialysis unit did not have guidelines in place to perform lower extremity assessments on any of its patients. The lack of current protocol created an opportunity for a quality improvement project and filled an educational need.

Patients, at Upstate Dialysis, undergo hemodialysis treatments three days weekly for an average of 3-5 hours each treatment (nocturnal patients 6-8 hours). The patients were under the direct care of a professional nurse for an average of 12 hours weekly or 64 hours a month. This allowed the nurse ample opportunity to perform a quick 5 minute lower extremity assessment. According to the South Carolina Department of Health and Environmental Control (SCDHEC) (2010), there must be at least one nurse per 10 hemodialysis stations.

Sample

Medical records were reviewed of all hemodialysis patients at Upstate Dialysis to determine individuals meeting project criteria of diabetics or over the age of 65 years. Patients with diagnosed peripheral vascular disease or prior lower extremity amputation were flagged for statistical purposes. Patient anonymity was protected by assigning a random number to patients meeting the inclusion criteria. Inclusion criteria consisted of

competent, hemodialysis patients at Upstate Dialysis in Greenville, SC who could speak and comprehend English. An explanation and description of the assessment process was provided. The quality improvement project met the criteria for an exemption status by the University of South Carolina internal review board since only de-identified data were used and this was a quality improvement project within the dialysis unit of the agency.

Application of Lewin's Framework to Reduce Barriers and Increase Support

Lewin's change theory was instrumental in gaining the support of management, medical staff, and patients. It provided a guideline for barrier reduction and cooperation from each member involved in the assessment team. Each stage of Lewin's theory builds on the previous stage until a common end point is reached during completion (refreezing).

The first stage in Lewin's theory, unfreezing, incorporated assessing the motivation and resources for change (Mitchell, 2013). The Upstate dialysis staff was actively involved in quality improvement and aggressively approached patient care. The motivation to learn and create advances in patient outcomes was a daily task and approached as a cohesive team. The members of the dialysis staff were unique in their ability to work as a team and each member was instrumental in the daily workings of the facility. There was a daily team meeting guided by a different specialty, social work, dietary, and so forth, to update the staff on concerns, education, and daily activities.

Barriers to change were addressed during the unfreezing stage. Education and colleague support played an important role in change within the unit. Education was provided through a power point presentation that included statistical information and mortality/morbidity data that illustrated current practices and the need for change.

A primary strategy to facilitate change/support in using a lower extremity assessment was cooperation and encouragement from key staff members. A lower extremity assessment algorithm was developed using evidence from the literature and a monofilament testing guide (U.S. Department of Health and Human Services, 2013).

Algorithm

The lower extremity algorithm (table A.2 in the Appendix) was created through a combination of best practice from diabetic, vascular, and nephrology literature. Due to the increased incidence of the three disease states in the ESRD population it was important to create a blending of the guidelines to capture the chronic complications of the hemodialysis patient.

The algorithm included a two page guide to a lower extremity assessment. The first page provided clear indicators for monofilament test results and dorsalis pedis pulse palpation while the second page was dedicated to skin and toe nail assessment. Each of these focus points had subcategories for each foot to document if the foot assessment showed a normal finding, an abnormal new finding, or an abnormal finding that was stable (not newly diagnosed). In an attempt to decrease complexity of the lower extremity algorithm a check off list was created to easily identify the source of the abnormal algorithm finding.

The professional nurses involved with direct patient care reviewed the assessment algorithm and asked any necessary questions. Education was provided through a power point review and reverse demonstration. Repetition was used as an educational strategy to promote comfort with the algorithm prior to initiation in the dialysis unit.

One of the largest barriers included active participation and cooperation from the dialysis patients. It is unclear whether the dialysis patients were reluctant to have their shoes removed due to odor, lack of hygiene, poor clothing care, or other factors and requires further review. However, as the monthly assessments became routine the patients began to ask the professional nurses to evaluate findings located during home care.

Mutual respect between the nurses and the patients was fostered through familiarity and frequent contact. The respect for the staff encouraged buy in from the patients. Bulletins were placed in the lobby and on the doors leading into and out of the dialysis clinic notifying the patients of upcoming lower extremity assessments allowing ample time for patient questions. Patients meeting project requirements were questioned by the nurse practitioner for concerns or clarification of the project purpose.

Procedure

The lower extremity assessment was performed monthly on every willing hemodialysis patient over the age of 65 years or with diagnosed diabetes for three consecutive months. Each professional nurse involved with the study was provided with a list of the patients (deidentified by number) that required lower extremity assessments to be performed that week. The procedure was directed by the designated lower extremity assessment algorithm.

First, a visual inspection was performed including nail length and cleanliness of the foot itself. This was followed by an assessment of the dorsalis pedis pulse, capillary refill, and presence of any alterations to the skin. Assessment findings were documented and any notations placed on the tool itself. Information to be added such as referrals to a

specialist was also noted. Referrals were made to specialists as necessary and the student was kept apprised of all proceedings. Data collection included the number of referrals created, number of individuals attending the referral appointment, and follow up care.

Outcome to be Measured

Outcomes were measured on a monthly basis. An accurate count of new referrals for vascular surgery, wound care, podiatry, and dermatology were collated following completion of the three month implementation of the designated algorithm. Referrals were expected to decrease as patients were established with a specialist; however, continuation of assessments was performed due to newly developing wounds, and patients lost to follow up or discharged.

Results were evaluated using McNemar's chi square (categorical) test. McNamers test is designed to provide marginal frequencies with information gathered from sources with two possible outcomes (The Regents of the University of California, 2006). Data were collated using a 2 x 2 table in which the two possible outcomes included whether referral was made/not made to a specialist and whether the assessment was performed/not performed by the nurses on a monthly rotation. McNamers test compared data from June to July, June to August, and July to August.

Data Analysis

Data analysis was performed using McNemars test and SAS statistical software. The data was placed into 2 x 2 contingency tables with either an answer of yes the patient was referred to a specialist following the completion of the assigned lower extremity assessment or no the patient was not referred to a specialist following completion of the

monthly assessment. The goal was to determine a correlation or difference between the two groups and tabulate outcomes of the sample.

Summary

A specific sample of the patients from Upstate dialysis were evaluated using a dedicated lower extremity assessment tool. The main goal of the tool was to determine if repetitive monitoring would increase the likelihood of early detection and intervention for potential vascular complications. Outcomes were measured by the number of referrals to specialists and McNemars test for correlation.

Kurt Lewin's Change Theory was the model for initiation of the assessment tool in the hemodialysis unit. Unfreezing was initiated through open communication, professional nurse involvement, and education. Barriers were recognized and overcome through cooperation and repeated education.

CHAPTER IV

RESULTS

The results of the three month quality improvement project were collated and placed into McNamer's statistical analysis to determine correlation. Results revealed that a dedicated lower extremity assessment algorithm is indeed need in this environment; however, a correlation was not noted between the groups referred and those not referred for the three month project period. As displayed in table 3.2, the result of McNamer test indicated there was not enough evidence to establish a correlation between the monthly dedicated assessments. The p-values were greater than 0.05; therefore, there is no statistical significance between monthly referrals created.

Description of Sample

The quality improvement project sample included 64 patients requiring chronic hemodialysis treatment at Upstate Dialysis in Greenville, SC. The demographics of the project population included 41 (64%) African Americans, 1 (2%) Asian, 2 (3%) Latino, and 20 (31%) Caucasian. The patients included 34 (53) men and 30 (47) women. Of the 64 project patients 21(33%) were previously diagnosed with peripheral vascular disease as a co-morbid condition, 49 (77%) of the patients were diabetic, 42 (66%) were over the age of 65 years, and 29 (45%) of the project patients were both diabetic and over the age of 65 years.

Analysis of PICO Question

The PICO question for this project was whether the use of a lower extremity assessment tool performed on adult hemodialysis patients over 65 years of age or diabetic increase the likelihood of early detection and intervention for potential vascular complications. The question required the performance of at least two actions following completion of the lower extremity assessment. The first action was that a referral be created for the patient if warranted and the second action required the patient to attend the appointment.

During the three month assessment trial there were a total of 11 (17%) referrals to specialists made, 6 in the month of June, 3 in the month of July, and 2 in the month of August. Each referral was created for a new patient and no individual was referred twice. Of the referrals created two were for wound care, one for vascular surgery, and eight were referrals for podiatry. Two of the patients referred for podiatry consults did not attend the appointment. They were provided with the name and number of the podiatrist and instructed to make an appointment based on their availability.

Table 4.1 below shows the results of the McNamers statistical analysis. Results did not indicate a statistically significant correlation between the three monthly assessments (see Table 4.2); however, there were new referrals created for lower extremity complications each month. The referrals for follow up by wound care, vascular, or podiatry were ongoing.

Table 4.1

Percentage of Referrals after Initiation of Designated Lower Extremity Assessment

Time Frame	Number of hemodialysis patient	Percentage	Number of hemodialysis patients not	Percentage not
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	referrals (yes)	referred	referred (no)	referred
June	6	9.38	58	90.63
July	3	4.69	61	95.31
August	2	3.13	62	96.88

The number of referrals were highest during the first monthly assessment (June) reflecting 6 (9.38%) of the 64 hemodialysis patients evaluated. Following the initial assessment the number of referrals began to decrease. The reason for the decrease is unclear; however, speculation is there may have been heightened awareness regarding foot protection due to ongoing education or that the patients were already being treated by a specialist based on the initial assessment and a new referral was not needed.

Table 4.2

<i>McNamer Test Results</i>		
Referral Months	Chi-Square Test	p-value
June	1	0.3713
July	0.2	0.6547
August	2	0.1573

Professional Nurses' Response

The professional nurses were quick to assist in educating the patients about the lower extremity assessment tool and to accurately perform each assessment on the designated week. They asked for clarification if necessary and kept the student apprised of any changes to patient care/treatment.

Unfortunately, one of the first patients to have the dedicated lower extremity assessment performed was referred and discovered to have osteomyelitis. An amputation of the great toe was performed followed by continued antibiotic therapy. The amputation

and follow up care may have reinforced the nurses' education and encouraged aggressive preventive management.

Although the professional nurses were quick to perform the assessment, they reported the number of pages to be difficult to manage. The two page lower extremity assessment was found to be challenging due to disruption of the flow of the assessment turning the page and having to keep up with more than one page. Many of the nurses adapted the tool and included all of the elements on one page often drawing on the foot illustrations provided for the monofilament test.

The main barrier the nurses reported prior to initiation of the algorithm was the amount of time it would take to complete the assessment; however, this did not seem to be a factor. The nurses did not report any difficulty with the assessment or decreased ability to perform allotted duties due to the time needed to perform the evaluations. On the contrary, many of the staff noted monthly changes in the foot reviews and actively participated in education with the patients and new staff.

The professional nurses actively participated in the dedicated lower extremity assessments and noted small changes in the patient's lower extremities. They created notes for follow up assessments, made notations in patient charts, and contacted family members concerning pressure points, toe nail care, and proper foot attire.

Patient Response to the Use of the Lower Extremity Algorithm

By the second month (July), the patients recognized the importance of proper foot care and asked the professional nurses to look at their feet. They took an active part in pointing out areas that were painful or redden during the dialysis session. By the end of

the third month a few of the patients that initially refused lower extremity assessments were willing to have them performed.

In summary, results revealed that a dedicated lower extremity assessment algorithm is needed in the hemodialysis unit; however, a correlation was not noted between the groups referred and those not referred for the three month project period. This may have been related to the small sample size and that the assessment was only followed for a 3 month period. Although a correlation was not noted, there were many encouraging aspects noted from the study. A primary interest was that the patients began to take an active role in their care and asked the professional nurses to look at changes they noted during home inspections. The patients were responding to the education presented and including it in their continued care outside the dialysis unit.

CHAPTER V

SUMMARY

The life expectancy of a hemodialysis patient is decreased when compared to individuals of the same age and gender in the general population. This is further complicated by comorbid conditions including advanced age and diabetes. Each of these factors plays a role in peripheral vascular complications and the risk of amputation and increased mortality.

In this quality improvement project, a dedicated lower extremity algorithm was initiated for a three month period at Upstate Dialysis in Greenville, SC. The primary focus of the project was to determine if a lower extremity assessment performed at monthly intervals could increase the incidence of early detection and intervention in individuals over the age of 65 years or with diabetes.

The end point reflected that there was not a correlation between the hemodialysis patients that were referred and those that were not referred; however, there were 11 new referrals made to specialists during the three month study period. It is unclear whether the prevalence was due to poor vision, increased incidence of peripheral neuropathy, lack of assistance at home, increased inflammation, mineral bone disorders, or a combination of these factors.

The lower extremity assessment algorithm will remain in place at Upstate Dialysis as part of their protocol. It will continue to be performed on a monthly basis on

diabetics and patients over the age of 65 years including newly admitted patients. Future plans are being discussed with Carolina Nephrology to include the use of a dedicated lower extremity algorithm in all the dialysis units in which they are medical directors. There is also limited discussion of possible angiograms to be performed on hemodialysis patients with vascular complications as noted by the dedicated algorithm at the Dialysis Access Center of Carolina Nephrology.

Recommendations:

Limitations to the project include the small number of participants and that data was only collected for a three month period. Recommendations include expanding the project to include a larger patient population, increasing the number of months the dedicated lower extremity algorithm is used for ongoing/follow up data collection, including data for potential health care cost versus savings and incorporating modifications made by the professional nurses to the algorithm. Records should be obtained from the referral base to track the referred hemodialysis patients and follow-up with patients that do not keep appointments. Many patients have difficulty with transportation to their appointments and require transportation from a van or ambulance service

Summary

Advances in medicine over the last century have revealed progress in almost every disease state with enhancements in stem cell research, robotic surgery, and powerful new pharmaceuticals, yet the mortality rate for end stage renal disease patients remains stagnant (USRDS, 2011). Many ESRD patients suffer from devastating diseases decreasing their likelihood for transplant and increasing their need for further medical

management. Members of this population face difficulties with vascular complications leading to lower extremity amputations and elevated mortality rates. Early assessment and intervention has proven to increase survival, yet it is often not addressed and only comes to light following loss and reflection.

Amputations are common in the hemodialysis population largely due to comorbid conditions including advanced age, diabetes, and vascular disease. These disease states increase the likelihood of limb loss due to diminished healing and elevated infection rates. Early intervention is a key component to limb salvaging; however, there is an absence of guidelines to aide in evaluating risk factors for vascular complications limiting accessibility.

Following a literature search that revealed limited and dated research for vascular complications for hemodialysis patients, a dedicated lower extremity assessment algorithm was created with information gleaned from diabetic and vascular guidelines. Additional information, metabolic bone disorders and access placement, was included from complications that are dialysis in nature.

The dedicated lower extremity algorithm was performed on all willing hemodialysis patients over the age of 65 years or diabetic at Upstate Dialysis in Greenville, SC. For three consecutive months the professional nurses performed lower extremity assessments noting any abnormalities in dorsalis pedis pulses, toe nail complications, alterations in skin, or irregular monofilaments tests. Patients requiring additional assessment skills were referred to specialists in wound care, vascular surgery, or podiatry.

At the end of the three months, eleven patients were referred to a specialist for follow up care. Although McNamers test did not reveal a correlation between the groups referred and those not referred, results display a need for a dedicated lower extremity algorithm in this environment.

There is also a need for further longitudinal research studies to evaluate patient outcomes related to long term complications of amputations, mortality, and increased rates of depression. Further research to determine the long term effects of a dedicated lower extremity algorithms in the hemodialysis units and whether follow up care is aiding in decreasing mortality rates should also be investigated.

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APPENDIX A

GLOSSARY

Table A.1

Definitions

Term	Definition	Source
Arteriovenous fistula	Abnormal anastomosis of an artery to a vein	Mayo Foundation for Medical Education and Research (MFMER), 2012
Arteriovenous graft	vascular access that connects an artery to a vein using a synthetic tube	National Kidney and Urologic Diseases Information Clearinghouse (NKUDIC), 2008
AMI	acronym for acute myocardial infarction; also known as a heart attack; interruption of blood flow to a portion of the heart	The Free Dictionary by Farlex, 2013
Calcification	calcium builds up in soft tissue, causing the tissue to stiffen or harden	Dugdale & Zieve, 2012
CVA	acronym for cerebrovascular accident; also known as a stroke; death of some brain cells due to lack of oxygen	Medterms, 2011
Diabetic Nephropathy	increased albumin/protein excretion from the kidneys	Gross, De Azevedo, Silveiro, Canani, Caramor, & Zelmanovitz, 2005

Hypercalcemia	increase in blood calcium; usually more than 10.5 milligrams per deciliter of blood.	The Free Dictionary by Farlex, 2013
Hyperparathyroid	increase in blood parathyroid level	The Free Dictionary by Farlex, 2013
Hyperphosphatemia	increase in blood phosphorus level	Medicinenet.com, 2013
Hypocalcemia	decrease in blood calcium level; total serum calcium of <8.5 mg/dL or ionized calcium of <4.6 mg/dL	Excelvier Inc. 2012
Inflammation	a local response to cellular injury marked by capillary dilation, leukocytic infiltration, redness, heat, pain, and serves as a mechanism initiating removal of damaged tissue	Merriam-Webster Dictionary
International Working Group of the Diabetic Foot (IWGDF)	classification system for research to bring about a common understanding of wound appearance using guidelines for perfusion, extent/size, depth/tissue loss, and sensation	Schaber, N., 2004
Metabolic Bone Disease	complication in chronic renal disease patients that includes disorders of mineral metabolism medical examination; perceived by the senses	Martin & Gonzalez, 2007
TIA	acronym for transient ischemic attack; decreased blood flow to the brain for a short period of time	MedlinePlus Medical Encyclopedia, 2012
Visual	perceived by vision or sight	Dictionary.com, 2010

Table A.2

Lower Extremity Algorithm

Monthly Lower Extremity Algorithm for Hemodialysis Patients with Diabetes or over the age of 65 years

Thigh accesses must be evaluated for wounds, aneurysms, and thrill prior to each dialysis session

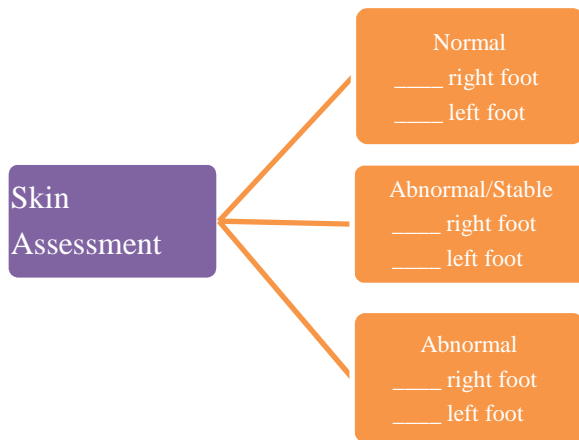
Normal-standard; usual, typical, or expected (Merriam-Webster, 2013)

Abnormal but stable-deviating from normal but not fluctuating/changing (Merriam-Webster, 2013)

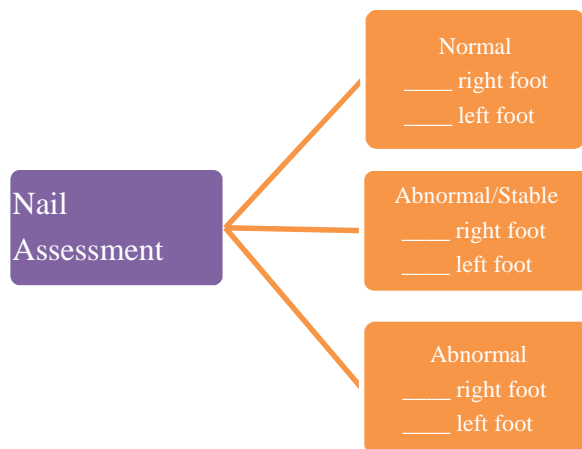
Abnormal-deviating from what is normal or usual, usually undesirable; frequently changing (Merriam Webster, 2013)

Monofilament Testing	Normal ____ right foot ____ left foot	Notes: _____ Referral: _____
	Abnormal/Stable ____ right foot ____ left foot	
	Abnormal ____ right foot ____ left foot	

Dorsalis pedis pulse	Normal ____ right foot ____ left foot	Notes: _____ Referral: _____
	Abnormal/Stable ____ right foot ____ left foot	
	Abnormal ____ right foot ____ left foot	



___ discoloration	Ulceration		
___ warm	___ location	___ size	___ depth
___ cold	___ granulation	___ slough	
___ eschar	___ drainage	___ pain	
Notes: _____			
Referral: _____			



___ brittle	___ dry
___ discoloration	___ fungal quality
___ missing	___ capillary refill < 2 seconds
Notes: _____	
Referral: _____	

Table A.3

Research Database

Bibliographic Citation	Study Type and Evidence Level	Sample Size Patient Characteristics	Intervention and Comparison	Length of Follow Up	Outcomes to be Measured	Threats to Validity and Reliability	Conclusions
1) Beckert,S., Sundermann, K., Wolf, S., Konigsrainer, A., Coerper, S. Haemodialysis is associated with changes in cutaneous microcirculation in diabetes mellitus. Diabetic Medicine. 2009; 26, 89-92	Cohort study <u>SIGN=</u> 2-	14 aged matched patients (7 diabetic and 7 non-diabetic) without foot ulceration	Cutaneous microcirculation was assessed using a micro-lightguide spectrophotometer to measure venous oxygen saturation and blood flow at 2 and 6 mm	Assessed at baseline and at 2 and 6mm with no follow up	Venous oxygen saturation and blood flow at 2 and 6 mm	Small study Not randomized Results may be from other factors No follow up	Haemodialysis is associated with changes in cutaneous microcirculation, differing in individuals with/without diabetes.
2) Boyle, J.P., Honeycutt, A.A., Venkat Narayan, K. M., Hoerger, T.J., Geiss, H., Thompson, T.J. Projection of diabetes burden through 2050: Impact of changing demography disease prevalence in the U.S. Diabetes Care. 2001: 24,11, 1936-1940	Meta-analysis with projection <u>SIGN=</u> 1-	varies	combined age, sex, race, diagnosed diabetes prevalence rates—predicted from 1980–1998 Sensitivity analyses performed by varying both prevalence rate and population projections	N/A	Trends in prevalence data from the National Health Interview Survey—with Bureau of Census population demographic projections	No Hispanic-projections Advances in diabetes, increasing life expectancy, screening, access to medical care not considered Assumes a linear increase in child diabetes	If recent trends in diabetes prevalence rates continue linearly over the next 50 years there will be dramatic increases in the number of Americans with diagnosed diabetes

Bibliographic Citation	Study Type and Evidence Level	Sample Size Patient Characteristics	Intervention and Comparison	Length of Follow Up	Outcomes to be Measured	Threats to Validity and Reliability	Conclusions
3) Broersma, A. Preventing amputations in patients with diabetes and chronic kidney disease. Nephrology Nursing Journal 2004; 31 (1) 53-62	Systematic review Review of literature <u>SIGN=</u> 1+	N/A	Risk factors for lower extremity amputation in diabetics-vasculopathy, biomechanics, plantar pressure, joint mobility, charcot, previous ulceration, amputation	N/A	Foot risk classification		Foot examinations can detect high risk conditions for which intervention may reduce amputation risk.
4) Combe, C., Albert, J. M., Bragg-Gresham, L., Andreucci, V. E., Disney, A, Fukuhara, S., Goodkin, D. A., Gillespie, B. w., Saito, A., Jadoul, M., Pisoni, R. L. The burden of amputation among hemodialysis patients in the dialysis outcomes and practice patterns study (DOPPS). American Journal of Kidney Disease, 2009; 54, 4, 680-692	Cohort study <u>SIGN=</u> 2++	29,838 patients in the DOPPS from 1996-2004	Comparison of new amputations involving hemodialysis patients in various countries. Factors also recorded malnutrition, anemia, diabetic status, sex, smoker	1996-2004	Number of amputations of individuals on hemodialysis –diabetic and non-diabetic	Does not list types of amputation	High prevalence (6%) and incidence (2.0 events/100 patient years at risk) of amputation in individuals on hemodialysis Individuals with diabetes have a >9 times incidence of new amputation

Bibliographic Citation	Study Type and Evidence Level	Sample Size Patient Characteristics	Intervention and Comparison	Length of Follow Up	Outcomes to be Measured	Threats to Validity and Reliability	Conclusions
5) Eggers P. W, Gohdes D., Pugh J. Nontraumatic lower extremity amputations in the Medicare end-stage renal disease population. <i>Kidney International</i> 1999; 56, 1524-1533.	Chart Review using ICD-9 codes for reference SIGN= 1++	Hospital bill data for the years 1991-1994 from the Health Care Financing Administration ESRD program management and medical information system (PMMIS)	Rates of lower extremity amputation with a focus on ESRD population (Medicare)	Follow up at 30 days, one year, two years	Rate of lower limb non-traumatic amputation in the ESRD population	Limited to Medicare patients listed in the PMMIS	LEA increased from 4.8/100 persons in 1991 to 6.2/100 persons in 1994. Rate among diabetic ESRD patients was 10 times > than those with diabetes only. Two thirds of the individuals died within 2 years of their first amputation.
6) Gomez, N. J. (1997). Wound care management in the end-stage renal disease population. <i>Advances in Renal Replacement Therapy</i> , 4(4), 390-396.	Expert opinion <u>SIGN=</u> 4	N/A	N/A	N/A	N/A	Information gathered was an expert opinion provided by a certified nephrology nurse, nurse consultant	Information was provided as to risk factors, assessment, and basic principles of wound care

Bibliographic Citation	Study Type and Evidence Level	Sample Size Patient Characteristics	Intervention and Comparison	Length of Follow Up	Outcomes to be Measured	Threats to Validity and Reliability	Conclusions
7) Ishimura, E., Okuno, S.Taniwaki, H., Kizu, A., Tsuchida, T., Shioi, A., Shoji, T., Tabata, T., Inaba, M., Nishizawa, Y. Different risk factors for vascular calcification in end-stage renal disease between diabetics and nondiabetics: The respective importance of glycemic and phosphate control. Kidney Blood Pressure & Research. 2008: 31, 10-15	Systematic review SIGN= 2++	N/A	Calcification differences among ESRD patients that are diabetic versus non-diabetic	N/A		Information used in combination with authors previous research	Importance of glycemic and phosphorus control in diabetics/nondiabetics to prevent calcification

Bibliographic Citation	Study Type and Evidence Level	Sample Size Patient Characteristics	Intervention and Comparison	Length of Follow Up	Outcomes to be Measured	Threats to Validity and Reliability	Conclusions
8) Joffe, R., Rodriguez-Benitez, P., Lopez-Gomez, J., Pérez-Garcia, R. Inflammatory syndrome in patients on hemodialysis. American Society of Nephrology, 2006:17, 274-280.	Expert Opinion SIGN= 4	N/A	Comparison of inflammatory markers, underlying disease, comorbidity, oxidative stress, vascular calcification, infections, genetic, immunologic, encapsulating peritoneal sclerosis, anemia, heart failure, obesity, HD technique	N/A	biochemical inflammatory markers to help identify patients at risk.		Hemodialysis patients with inflammation have a poorer prognosis.
9) Locking-Cusolito, H., Harwood, L., Wilson, B., Burgess, K., Elliot, M., Gallo, K., Ische, J., Lawrence-Murphy, J., Ridley, J., Robb, M., Taylor, C., Tigert, J. Prevalence of risk factors predisposing to foot problems in patients on hemodialysis. Nephrology Nursing Journal, 2005:32,373-84	One time only assessment of patient risk factors <u>SIGN=</u> 1+	232 patients	Single assessment to identify the prevalence of risk factors that predispose hemodialysis patients to foot complications	N/A	Presence of prior amputation, smoking status, neuropathy, palpable pedal pulses	Limited to one hemodialysis unit in a large, urban, academic setting Number of native Canadians participating in the study demographics	Patients are at considerable risk for foot complications

Bibliographic Citation	Study Type and Evidence Level	Sample Size Patient Characteristics	Intervention and Comparison	Length of Follow Up	Outcomes to be Measured	Threats to Validity and Reliability	Conclusions
10) Mahnensmith, R.L., Zorzanello, M., Hsu, Y., Williams, M. E. A quality improvement model for optimizing care of the diabetic end-stage renal disease patient. Seminars in dialysis. 2010; 23, 206-213	Systematic review <u>SIGN=</u> 1+	N/A	Comparison of three different models CKD stage 4 and 5 (diabetic patient), first 30 days of dialysis (diabetic), fist 90 days of dialysis	N/A	Care priorities glucose, nutrition, cardiac , vascular, hemoglobin care, optimal dialysis	Diabetic patient only Plan of care was not individualized	Diabetics with CKD are more likely to experience glycemic fluctuations, cardiovascular co-morbidity and early mortality. Reducing morbidity requires a dedicated clinician and comprehensive care
11) Malluche, H. H., Mawad, H., Claude-Monier-Faugere, M. The importance of bone health in end-stage renal disease: out of the frying pan, into the fire? Nephrology Dialysis Transplantation 2004; 19 (1), 9-13.	Case Control <u>SIGN=</u> 2-	N=43 dialysis patients 16 with low turn over bone disease, 7 with hyper-parathyroid bone disease, and 20 with mixed uraemic osteodystrophy	Comparison of intestinal calcium absorption, calcium efflux, calcium accretion	N/A	Correlation between plasma calcium efflux and bone calcium accretion	Small population	Recent changes in bone disease with a decrease in prevalence of mixed uraemic osteodystrophy and osteomalacia
12) Martin, K. J., González, E. A. Metabolic bone disease in chronic kidney disease. American Society of Nephrology, 2007;18, 875-885	Systematic review <u>SIGN=</u> 1++	N/A	N/A	N/A	N/A	N/A	Recent advances over the last four decades has increased understanding of the pathophysiology of metabolic bone disease

Bibliographic Citation	Study Type and Evidence Level	Sample Size Patient Characteristics	Intervention and Comparison	Length of Follow Up	Outcomes to be Measured	Threats to Validity and Reliability	Conclusions
13) Mickley, V. Steal syndrome—strategies to preserve vascular access and extremity. Nephrology Dialysis Transplant, 2008:23, 19-24.	Expert opinion with systemic review <u>SIGN=</u> 4	N/A	N/A	N/A	N/A	None	
14) Miller, C. D., Robbin, M. L., Barker, J., Allon, M. Comparison of arteriovenous grafts in the thigh and upper extremities in hemodialysis patients. Journal of the American Society of Nephrology, 2003:14, 2942-2947.	Cohort study <u>SIGN=</u> 2+	409 grafts placed; 346 in the upper extremities and 63 in the thighs	Outcomes of all grafts (upper extremities and thigh) Comparison of graft survival, infection, technical failure, survival rate	3.5 years from January 1, 1999 to June 30, 2002	Number of grafts placed (type), number with technical failure, thrombus, infection, survival rate		Comparison of thigh grafts is comparable to upper extremity grafts
15) Ndip, A., Rutter, M. K., Vileikyte, L., Vardhan, A., Asari, A., Jameel, M., Tahir, H., Lavery, L. A., Boulton, A., J. M. Dialysis treatment is an independent risk factor for foot ulceration in patients with diabetes and stage 4 or 5 chronic kidney disease. Diabetes Care, 2010:33, 1811-1816.	Case Control study <u>SIGN=</u> 2+	326 patients with diabetes and CKD stage 4 or 5 or with ESRD requiring renal replacement therapy	Prevalence of DPN, PAD, prior amputation, prior foot ulceration, prevalent foot ulceration	N/A	Prevalence of DPN, PAD, prior amputation, prior foot ulceration, prevalent foot ulceration	Limitations included ethnic considerations. The majority of the individuals were white. The sample size to be sufficient to compare the site of foot ulceration between the two	

Bibliographic Citation	Study Type and Evidence Level	Sample Size Patient Characteristics	Intervention and Comparison	Length of Follow Up	Outcomes to be Measured	Threats to Validity and Reliability	Conclusions
16) Nichols-English & G., Poirier, S. Optimizing adherence to pharmaceutical care plans. <i>Journal of American Pharmaceutical Association</i> , 2004;40 (4), 475-485.	Systematic review <u>SIGN=</u> 1+	N/A	N/A	N/A	N/A	Primarily aimed to pharmacotherapy	Provides information to encourage adherence to medication management
17) O'Hare, A. M., Feinglass, J., Reiber, G. E., Rodriguez, R. A., Daley, J., Khuri, S., ... Johansen, K. L. (2004). Postoperative mortality after nontraumatic lower extremity amputation in patients with renal insufficiency. <i>Journal of the American Society of Nephrology</i> , 15, 427-434.	Cohort study <u>SIGN=</u> 2++	16,944 patients undergoing their first amputation recorded by NSQIP from Jan 1, 1994 to Sept 30, 2001	Recorded mortality rates after lower extremity amputation for those with compromised renal function	30 days postop	Mortality rates for patients with compromise renal function 30 days postop first amputation	Data included only those with first amputation in the NSQIP database	Renal insufficiency increases the risk of mortality following amputation. Individuals with renal insufficiency were more likely to require repeat amputation within 30 days of the initial surgery

Bibliographic Citation	Study Type and Evidence Level	Sample Size Patient Characteristics	Intervention and Comparison	Length of Follow Up	Outcomes to be Measured	Threats to Validity and Reliability	Conclusions
18) O'Hare, A. & Johansen, K. Lower-extremity peripheral arterial disease among patients with end-stage renal disease. Journal of the American Society of Nephrology, 2001;12, 2838-2847	Systematic review <u>SIGN=</u> 1++	123 VAMC using NSQIP N=16994	Compared degree of renal insufficiency and postop mortality at 30 days following lower extremity amputation	30 days	Postop death within 30 days of amputation	Limited to individuals listed in the NSQIP database Cannot determine if the individuals on dialysis were chronic/acute renal failure—eliminated those with acute preoperative renal insufficiency	Postop mortality was 16% in dialysis patients. There is a need for improving the care of patients with renal disease undergoing lower extremity amputation
19) Plantinga, L. C., Fink, N. E., Coresh, J., Sozio, S. M., Parekh, R. S., Melamed, M. L., Powe, N. R., Jaar, B. G. Peripheral vascular disease-related procedures in dialysis patients: predictors and prognosis. Clinical Journal American Society of Nephrology, 2009;4 (10), 1637-1645	Prospective cohort study <u>SIGN=</u> 2+	1041 incident dialysis patients 217 underwent PVD procedure following initiation of dialysis	Examine the risk factors and prognosis in dialysis patients undergoing PVD procedures	N/A	Determine factors and prognosis following PVD procedures. Measurement of fibrinogen, CRP, blood pressure, albumin	Patients were from the CHOICE study	Prognosis following PVD intervention, after initiation if dialysis, is poor and risk factors differ with diabetes status.

Bibliographic Citation	Study Type and Evidence Level	Sample Size Patient Characteristics	Intervention and Comparison	Length of Follow Up	Outcomes to be Measured	Threats to Validity and Reliability	Conclusions
20) Razeighi, E., Omati, H., Maziar, S., Khashayar, P., Mahdavi-Mazheh, M. Chronic inflammation increases risk in hemodialysis patients. Saudi Journal of Kidney Diseases and Transplantation 2008: 19 (5), 785-789.	Cross sectional <u>SIGN+=</u> 2+	114 hemodialysis patients	Comparison of labs and physical features including CRP, albumin, hemoglobin, transferring, BMI, length of dialysis, triceps, skin fold thickness, CRP IL-6, hemoglobin, serum ferritin, triglycerides, cholesterol, total protein, mid-arm circumference, mid arm muscle circumference, Kt/V	None listed	Relationship between labs and physical features leading to increased CRP levels	CRP was measured once during the study Limited background information	Negative relationship between CRP and albumin, transferring and hemoglobin CRP can aide in management of inflammation
21) Young, E.W., Albert, J.M., Satayathum, S., Goodkin, D.A., Pisoni, R.L., Akiba, T., Kurokawa, K., Bommer, J., Piera, L., Port, F. K. Predictors and consequences of altered mineral metabolism: The dialysis outcomes and practice patterns study. Kidney International 2005: 67, 1179-1187	Case control <u>SIGN=</u> 2+	Hemodialysis units N=307, Patients N=17236	Association between mineral metabolic abnormalities and mortality in hemodialysis patients in 7 countries participating in the DOPPS	varies	Evaluated how altered levels of phosphorus, calcium, calcium-product influences soft tissue calcification	Dialysate calcium concentration varied by continent Potential inaccuracies in reporting Large groups in various countries to manage data	Laboratories for many hemodialysis patients exceed the recommended range. Mortality and PTX risks are associated with altered mineral metabolism values.

Bibliographic Citation	Study Type and Evidence Level	Sample Size Patient Characteristics	Intervention and Comparison	Length of Follow Up	Outcomes to be Measured	Threats to Validity and Reliability	Conclusions
22) Zimmermann, J.,Herrlinger, S., Pruy, A., Metzger, T., & Wanner, C. (1999). Inflammation enhances cardiovascular risk and mortality in hemodialysis patients. Kidney International, 55(2), 648-658.	Cohort study SIGN= 2++	280 white patients on hemodialysis at the University of Würzburg and three other clinics.	Lab values including serum CRP, lipids, apolipoproteins (apo) A-I and B, lipoprotein(a), fibrinogen, albumin, serum amyloid A	Follow up 24 months	Mortality over a 24 month period	All patients were white from selected dialysis units	An acute inflammatory process is a potential indicator of cardiovascular mortality in hemodialysis patients.