

PREVENTING PROGRESSION OF END STAGE RENAL DISEASE: A
SYSTEMATIC REVIEW OF PATIENT-PROVIDER COMMUNICATION IN
PRIMARY CARE

by

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ABSTRACT

Background: Chronic kidney disease (CKD) affects approximately 26 million individuals in the United States and is a top priority in the objectives for Healthy People 2020. Despite efforts to improve awareness, discussion of CKD is often minimal or ineffective in the primary care setting. This leads to a lack of patient awareness and knowledge of self-care skills to prevent or slow progression of the disease. A lack of communication of has been attributed to the provider's lack of confidence and knowledge to discuss CKD and to avoid unnecessary stress.

Purpose: The purpose of the DNP project is to provide a systematic review of patient-provider communication processes used to influence self-management or behavioral change in primary care and propose a tool to enhance communication and slow progression of CKD.

Methods: A systematic review was conducted following the method guidelines of the Cochrane Collaboration. Six electronic databases were searched. Inclusion criteria were adult humans, primary research studies, systematic and literature reviews, focus on communication of self-management or behavioral change strategies, primary outcomes of improving self-management and/or patient outcomes and availability of full-text online or by request.

Outcomes: Of the 5765 articles initially identified, 28 studies met inclusion criteria. The studies revealed a lack of evidence directed towards CKD and communication was not directly addressed in a majority of the studies. Interventions most successful in improving patient outcomes were individualized, elicited collaboration or interaction with the patient and provider, were motivational or encouraging and aided in barrier identification and problem solving. A

communication tool was developed from the evidence in order to stimulate more meaningful conversation between the patient and provider.

CHAPTER I: INTRODUCTION

Chronic illnesses are the leading cause of death and disability in the United States (U.S.) and account for 75% of healthcare spending (Centers for Disease Control National Center for Chronic Disease Prevention and Health Promotion [NCCDPHP], 2014). In the U.S. there are approximately 133 million individuals living with at least one form of chronic illness (NCCDPHP, 2012). Of these individuals, those diagnosed with diabetes and hypertension have a higher likelihood of developing comorbidities such as chronic kidney disease (CKD) (National Kidney Foundation [NKF], 2015); CKD affects at least 29 million individuals in the U.S. and its population is rapidly increasing (Boulware, Carson, Troll, Powe, & Cooper, 2009; NKF, 2015). Despite efforts to promote awareness and evidence-based (EB) guidelines for screening and managing CKD, gaps remain in early detection and prevention (Narva et al., 2010).

Once the kidneys are damaged, without intervention, they will continue to deteriorate eventually leading to end stage renal disease [ESRD] (Walker, Marshall, & Polaschek, 2013). With ESRD, patients require renal replacement therapy (RRT) or renal transplantation for survival (Boulware et al., 2009). Primary care providers (PCPs) are in the optimal position to relay the necessary education and strategies to prevent the development or slow progression of CKD; they are often the first point of care and can provide the most impact prior to or during the early stages of the disease (Walker et al., 2013). However, research suggests that discussions of CKD or CKD risk factors in primary care are often minimal due to the provider's lack of knowledge and confidence (Couser, Remuzzi, Mendis, & Tonelli, 2011; Greer, Cooper, Crews, Powe, & Boulware, 2011; Taal, 2013).

The purpose of this DNP project is to provide a systematic review and analysis of patient-provider communication processes used to influence self-management or behavioral change to prevent the development or slow progression of CKD. Furthermore, the DNP project will propose a communication tool based on the current best evidence to improve patient-provider communication. The first chapter will include a general overview of CKD and integrate discussions regarding pertinent risk factors, prevalence of CKD, screening, diagnostic criteria, consequences, burden of disease and statement of the problem. This chapter will also describe the significance of improving patient-provider communication to the Doctor of Nursing Practice (DNP) and society.

Background

CKD is a disease in which there is a gradual loss of kidney function and over time results in an accumulation of harmful toxins in the blood due to poor filtration (NKF, 2015). It is characterized by an estimated glomerular filtration rate (eGFR) of less than 60 ml/min/1.73 m² or the presence of protein in the urine (proteinuria) for greater than three months (Couser et al., 2011; NKF, 2002, 2015). Though kidney function declines each year after age forty, eGFR persistently below 60 ml/min/1.73 m² is more than the expected decline due to age (Mitch, 2012). Nephrotoxins, systemic diseases and intrinsic disorders of the kidneys can further insult the natural decline of kidney function and may lead to irreversible damage. Examples of these include contrast, medications, diabetes, hypertension, polycystic disease and obstructive disease (Mitch, 2012).

Nephrons and Kidney Function

The nephron is the functional unit of the kidneys and is comprised of the glomerulus, proximal tubule, loop of Henle, distal tubule and collecting duct. There are roughly 0.75 to 1.25 million nephrons in each kidney; once damaged, these nephrons cannot be reproduced (Mitch, 2012). The nephrons are responsible for endocrine mediation, regulating the body content of electrolytes and fluid volume, regulating blood pressure and excreting wastes (Mitch, 2012). Though the body will compensate for lost nephrons, if the original source of damage is not eliminated or if future damage is not prevented, the kidneys will continue to deteriorate leading to ESRD (Mitch, 2012). The intact nephron hypothesis suggests that “the sum of the function of all remaining nephrons determines the whole kidney’s GFR” (Mitch, 2012, pg.811). GFR is the most accurate estimate of remaining kidney function and is used for disease staging according to NKF guidelines (Mitch, 2012; NKF, 2002).

Disease Staging

Severity of the disease is classified by five stages ranging from Stage 1—kidney damage with normal or GFR greater than $90 \text{ ml/min/1.73 m}^2$ to Stage 5—kidney failure (NKF, 2002). The early stages of CKD are often asymptomatic and without proper screening or testing, can be overlooked or mistreated (Boulware et al., 2009). Staging of the disease is pertinent for the proper monitoring and management of complications related to CKD; each stage presents with its own issues and treatment goals (Kraut, 2013). Table 1 provides a summary of guidelines for classification of CKD according to the NKF (2002) Kidney Disease Outcomes Quality Initiative (KDOQI).

TABLE 1. *NKF KDOQI Guidelines for CKD Classification*¹

Stage	Description	GFR (mL/min/1.73 m ²)
1	Kidney damage with normal or increased GFR	≥90
2	Kidney damaged with mild decrease in GFR	60-89
3	Moderate decrease in GFR	30-59
4	Severe decrease in GFR	15-29
5	Kidney failure	<15 or need for dialysis

¹National Kidney Foundation (2002). KDOQI clinical practice guidelines for chronic kidney disease: Evaluation, classification and stratification. Retrieved from http://www.kidney.org/professionals/KDOQI/guidelines_ckd/p4_class_g1.htm

Symptoms

As previously mentioned, patients with kidney disease frequently present with few or no symptoms (Boulware et al., 2009). Though patients may appear asymptomatic, unknowingly, CKD causes destruction of organ function and contributes to electrolyte abnormalities, hormonal imbalances and anemia (Kraut, 2013). Over time, this destruction becomes irreversible and at the late stages of CKD, symptoms become more prevalent (Kraut, 2013; NKF, 2015). Symptoms of stage three to five include fatigue, trouble sleeping, muscle weakness, decreased libido, decreased appetite, nausea and vomiting, and subtle mental status changes (Kraut, 2013; NKF, 2015). Because these symptoms occur with other diseases, CKD may be overlooked if providers rely solely on GFR and serum creatinine for diagnosis (Kraut, 2013). This highlights the importance of utilizing evidence-based guidelines to screen all patients at risk for CKD in order to prevent or minimize rapid progression of the disease.

Prevalence

CKD is a well-established public health concern yet surveillance protocols are lagging in their ability to illustrate the burden of the disease (Shahinian et al., 2013). Its plaguing presence in the U.S. population is also a priority in the objectives for *Healthy People 2020* (U.S.

Department of Health and Human Services [USDHHS], 2013). However, despite efforts to improve awareness and detection, there are obstacles in identifying those with CKD (United States Renal Data System [USRDS], 2013). Current datasets lack the biochemical information to accurately capture its true prevalence in the population (USRDS, 2013). According to USRDS (2013), the population of individuals enrolled in Medicare with CKD increases by 1.2 million each year. With the population of Medicare patients and those enrolled in private insurance, there is an estimated 29 million individuals diagnosed with some form of renal disease (USRDS, 2013). This equates to a prevalence of 1,700 per 1,000,000 population and is expected to increase if early interventions are not established and patient awareness of CKD is not improved (Shahinian et al., 2013).

Risks

Between 1999 and 2010, CKD was most commonly diagnosed among those of African American and Mexican American descent. These individuals accounted for roughly 18-19% of the total population respectively (CDC, 2014). Additionally, diabetes and hypertension were the most prevalent causes of CKD (USRDS, 2013). Based on Medicare statistics, 48% of the enrolled population diagnosed with CKD had a coexisting diagnosis of diabetes and 92% had a coexisting diagnosis of hypertension (USRDS, 2013). In the current Medicare population, patients with diabetes, hypertension or cardiovascular disease are two to four times more likely to have CKD compared to those without diagnosis (USRDS, 2013). When patients are not aware of their risks and self-management behaviors are not initiated in order to adequately control these risks, patients are likely to develop CKD and progress quickly to ESRD (Levey & Coresh, 2012; McClellan, 2005; Taal, 2011).

Diabetes. Glycemic control can be optimally achieved in the primary care setting. This is particularly important to the DNP in this setting, because without intervention, diabetes is a risk factor for rapid progression of CKD (Levey & Coresh, 2012). Though it is normal after age forty to lose 0.75 - 1.00 ml/min of GFR per year, high risk factors such as diabetes can cause a loss of 4 ml/min per year (Levey & Coresh, 2012). At this rate, an individual with diabetes from onset of CKD stage three to ESRD would be 12 years or less (Levey & Coresh, 2012). Approximately fifteen to 35% of individuals with type 1 or type 2 diabetes will develop some form of kidney damage (Caramori & Rossing, 2016). Therefore, it is essential that PCPs identify these patients at risk and begin the discussion early to be more pro-active. As the prevalence of diabetes is expected to nearly double to 522 million people worldwide (Reutens, 2013), the rates of diabetic kidney disease will continue to rise if improvements are not made in the management of these patients.

Hypertension. Hypertension affects at least 50 million people in the U.S. with individuals over 60 years of age being the majority (Chanda & Fenves, 2009). Additionally, hypertension is considered as both a cause and complication of CKD and affects approximately 50% to 75% of the disease population (Chanda & Fenves, 2009). Although the prevalence of hypertension is high, less than 50% of individuals have ideal blood pressure control (Bakris & Ritz, 2009; Chandra & Fenves, 2009). Hypertension is defined as a blood pressure greater than 140/90 mm Hg and for those with kidney damage, blood pressure should be less than 130/80 mm hg (Bakris & Ritz, 2009). Risk factors such as low GFR, obesity, African American decent, increased age, male gender, diabetes, proteinuria and hypertriglyceremia account for the prevalence of hypertension in those diagnosed with CKD (Chanda & Fenves, 2009). Without

adequate control, hypertension will cause rapid progression of CKD; hypertension is the second leading cause of ESRD (McClellan, 2005).

Cardiovascular disease (CVD). CVD is considered a cause and consequence of CKD; those with CVD are likely to develop CKD and those with CKD are likely to develop CVD (Taal, 2011). In a study of Medicare patients, approximately 60.4% of patients with stage 3 or more severe CKD had heart failure and 51.7% had a history of myocardial infarction (Taal, 2011). This may be caused by the effects of decreased renal perfusion in heart failure and atherosclerosis of the renal arteries (Taal, 2011).

Others. Additional risk factors include male gender, age greater than 80 years, smoking, hyperlipidemia and familial history of kidney disease (Mitch, 2012), USRDS, 2013). As the current population ages and the prevalence of obesity, diabetes and hypertension continues to rise, the U.S. population diagnosed with CKD will rise exponentially in the coming years (James, Hemmelgarn, & Tonelli, 2010). Understanding the risks associated with CKD is essential for PCPs because they manage a large majority of the population at risk (Walker et al., 2013). Due to the progressive nature of the disease, early interventions can influence rate of progression and may prevent or prolong ESRD (Mitch, 2012).

Screening and Diagnostic Criteria for CKD

Screening. The NKF recommends that all patients should be assessed for risk factors that may lead to the development of CKD (Martinez-Ramirez, Cortes-Sanabria, Rojas-Campos, Hernandez-Herrera, & Cueto-Manzano, 2013; NKF, 2015). High risk factors include individuals with known family history of renal disease, diabetes, hypertension, etc. as previously discussed (National Guideline Clearinghouse [NGC], 2013). For those identified as high risk, markers for

kidney damage must be evaluated. Recommended tests include: blood pressure measurement, serum creatinine, electrolytes and blood urea nitrogen (BUN), eGFR, protein-to-creatinine ratio, urinalysis and fasting lipid profile (NGC, 2013). If eGFR is less than 60 ml/min the test should be repeated within 90 days. Additionally, blood pressure should be monitored at least twice a year and eGFR every one to two years (NGC, 2013).

Though evidence suggests that early interventions can prevent or prolong the progression of CKD, the U.S. Preventative Services Task Force (USPSTF) does not recommend routine CKD screening in asymptomatic adults (Moyer, 2012). The USPSTF states that there is insufficient evidence to determine the risk versus benefit of routine screening (Moyer, 2012). Moreover, controversies remain whether or not routine screening is useful in the general population (Taal, 2012; Van der Tool et al., 2014). However, the USPSTF does state that recommended screening is feasible in primary care (Moyer, 2012).

Potential harm from screening include: healthcare burden of referral to secondary care, psychological effects of a CKD diagnosis and potential difficulty of obtaining health insurance or employment due to diagnosis (Taal, 2012). Screening for CKD in all patients with diabetes and hypertension is recommended by the American Diabetes Association and National Institutes of Health's Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood pressure (Moyer, 2012).

Diagnostic criteria. The sole use of serum creatinine as a marker of CKD can lead to under detection of early stages of the disease (James, Hemmelgarn, & Tonelli, 2010). Serum creatinine is a byproduct of muscle metabolism and can be falsely low in individuals with low muscle mass. Populations that may be affected by this include the older population, individuals

with malignancy and individuals with chronic liver disease (Kraut, 2013). The NKF recommends utilizing eGFR for predicting and classifying the stages of CKD (NKF, 2002). In conjunction with serum creatinine, eGFR can aid in predicting CKD; CKD is diagnosed when eGFR is <60 ml/min for three consecutive months (NKF, 2002). Testing for protein in the urine is also useful in the early diagnosis of CKD and can be easily facilitated along with eGFR in the primary care setting (Vassalotti, Stevens, & Levey, 2007). It is also important to note that diagnosis should not be based on a single measurement of eGFR and that results must be confirmed (Martinez-Castelao et al., 2013).

Additional markers for kidney damage include one or more of the following: albumin to creatinine ratio of 30 mg/g, urinary sediment abnormalities, abnormalities due to tubular disorders, abnormalities detected by histology, structural abnormalities and history of kidney transplantation (Stevens & Levin, 2013). CKD can also be diagnosed if any of the above is present for greater than three months (Couser et al., 2011). Though current guidelines for CKD utilize eGFR and albuminuria for diagnosis, studies suggest that eGFR and albuminuria are insensitive biomarkers. Additionally, these studies discuss that further research is needed to confirm the benefits of utilizing other biomarkers such as serum Cystatin C for increasing sensitivity for early identification of CKD (Fassett et al., 2011; Levey et al., 2011).

Calculating eGFR. Though glomerular filtration rate (GFR) is considered the best overall measurement of kidney function, it is an expensive laboratory test and may not be feasible in the primary care setting (Vassalotti et al., 2007). eGFR provides an alternative by utilizing an established equation (Vassalotti et al., 2007). The most validated and commonly used

equation is the Modification of Diet in Renal Disease (MDRD). Below is a list of equations to calculate eGFR for adults greater than 18 years of age.

TABLE 2. *Equations for Calculating eGFR.*

Name	Equation
MDRD ¹	$GFR \text{ (mL/min/1.73 m}^2\text{)} = 175 \times (S_{cr})^{-1.154} \times (\text{Age})^{-0.203} \times (0.742 \text{ if female}) \times (1.212 \text{ if African American})$
CKD EPI ^{1,2}	$GFR = 141 \times \min(S_{cr}/\kappa, 1)^\alpha \times \max(S_{cr}/\kappa, 1)^{-1.209} \times 0.993^{\text{Age}} \times 1.018 \text{ [if female]} \times 1.159 \text{ (if African American)}$

¹ National Kidney Disease Education Program [NKDEP] (2014). Estimating GFR. Retrieved from <http://nkdep.nih.gov/lab-evaluation/gfr/estimating.shtml>

² This equation must be used in conjunction with the table found on the NKDEP website (<http://nkdep.nih.gov/lab-evaluation/gfr/estimating.shtml>)

Complications of CKD

CKD is the ninth leading cause of death among the U.S. population (Centers for Disease Control and Prevention [CDC], 2012). It is also a risk multiplier for CVD, stroke, diabetes, hypertension, decreased immunity and increased hospitalization (Tonelli & Riella, 2014).

Though the mean annual eGFR decline varies between individuals with CKD, factors such as proteinuria, hypertension, diabetes, hyperlipidemia, old age, obesity and smoking are known predictors for rapid decline of kidney function (Qaseem, Hopkins, Sweet, Starkey, & Shekelle, 2013). Common complications that can be monitored and prevented in primary care include anemia, mineral and bone disorders and ESRD requiring renal replacement therapy (RRT) or transplantation (Thomas, Kanso, & Sedor, 2008; Turner, Bauer, Abramowitz, Melamad, & Hostetter, 2012). These complications are described in further detail below.

Anemia. Anemia is defined as a hemoglobin level of less than 13 g/dL in men and postmenopausal women and less than 12 g/dL in premenopausal women (Thomas et al., 2008).

CKD-associated anemia is prevalent in 50% of the individuals with CKD (Thomas et al., 2008). The most common cause of anemia is due to the decreased erythropoietin synthesis; erythropoietin is responsible for stimulating the growth and differentiation of red blood cells in the bone marrow (Thomas et al., 2008). Anemia increases an individual's risk of morbidity and mortality from cardiovascular complications and may subsequently lead to further decline in kidney function (Thomas et al., 2008).

Mineral and bone disorders. In 2005, the NKF/Kidney-Dialysis Outcome Quality Initiative (K-DOQI) developed a priority action plan in order to standardize the definition of CKD-mineral and bone disorders (CKD-MBD). CKD-MBD is defined as a cluster of disorders caused by CKD-related systematic alterations in mineral and bone metabolism (Cozzolino et al., 2014). The kidneys are the primary site for phosphate excretion and synthesis of vitamin D. When phosphate excretion and vitamin D synthesis is reduced due to kidney damage, calcium levels begin to fall and parathyroid hormone secretion is increased (Thomas et al., 2008). This may result in mineral and bone alterations identified by one or more of the following: laboratory abnormalities of calcium, inorganic phosphorus, parathyroid hormone and vitamin D, bone abnormalities or calcification of the vasculature or other soft tissues (Cozzolino et al., 2014). Moreover, hyperphosphatemia significantly increases an individual's mortality rate and is one of the most important risk factors associated with CVD in CKD patients (Thomas et al., 2008).

RRT or transplantation. The primary goal of CKD management is to prevent or prolong the progression to ESRD. Without intervention, patients will rapidly progress to ESRD requiring RRT or transplantation for survival (Mitch, 2012). When GFR is less than 15%, the kidneys are not capable of maintaining fluid balance, filtering toxins and regulating essential electrolytes

(NKF, 2002). At this point, patients should be referred to a nephrologist for ESRD management (Chan, Dall, Fletcher, Lu, & Trivedi, 2007). However, ESRD is associated with a large symptom burden that can be managed in the primary care setting (O'Connor & Corcoran, 2012). Patients have reported up to nine symptoms relating to ESRD such as pain, lack of energy, pruritus, muscle cramps, restless leg syndrome, dyspnea and edema (O'Connor & Corcoran, 2012).

Patient-Provider Communication

For the purposes of this DNP Project, patient-provider communication is defined as any verbal or written exchange of CKD or health-related information between the patient and provider. These are statements or discussions specifically targeted towards influencing self-management or behavioral change in order to prevent development or slow progression of CKD. In order to improve patient outcomes related to CKD, patients must adhere to dietary, lifestyle and medication guidelines which require not only knowledge of the disease, but also the desire to change. Therefore, effective patient-provider communication is essential for molding the individual's perception of his or her disease and subsequently influences their decisions to change (Boulware et al., 2009).

PCPs are often the first point of contact for individuals with or at high risk for CKD and are in the best position to relay crucial education and strategies to prevent or slow the progression of the disease (Walker et al., 2013). Additionally, patients rely on the provider's expertise and knowledge, both of which can be a significant influence on the patient's behavior and self-management choices (Ben-Arye & Visser, 2012). In one study regarding complementary and alternative medicine, researchers reported that a physician's recommendation was the most influential factor in using herbal medication (Ben-Arye & Visser,

2012). Recent studies regarding patient-provider communication and CKD determined that there are minimal discussions of CKD which are often only related to the discussion of laboratory results (Couser et al., 2011; Greer et al., 2011; Taal, 2013). Improvement in patient-provider communication of self-management or behavioral change strategies is warranted especially among those at high risk for developing CKD in the primary care setting which will be addressed by this DNP Project.

Statement of Problem

The population of CKD is exponentially rising in parallel to the aging population and increasing rates of diabetes, hypertension and obesity among the U.S. population (Tonelli & Riella, 2014). Chronic conditions like these are managed in the primary care setting and subsequently the majority of patients with known or unknown CKD are only seen by a primary care provider (PCP) (Qaseem et al., 2013; USRDS, 2013; Yaqub et al., 2013). Studies also show that patients are more likely to see a PCP or cardiologist following CKD diagnosis than a nephrologist (USRDS, 2013).

Regardless of the optimal opportunities to screen and initiate early interventions, discussions of CKD are frequently minimal in the primary care setting (Qaseem et al., 2013; Wright Nunes et al., 2011; Yaqub et al., 2013). When patient-provider communication is ineffective or lacking, patients are less aware and less knowledgeable about CKD. This may lead to poor outcomes such as rapid progression of ESRD, early initiation of dialysis and unnecessarily high health care costs (USRDS, 2013; Wright Nunes et al., 2011). Lack of communication is attributed to reasons such as the PCP's lack of confidence to discuss CKD, to avoid unnecessary stress when complications are not present and lack of PCP knowledge of

CKD (Couser et al., 2011; Greer et al., 2011; Taal, 2013). Minimal patient-provider communication limits opportunities to provide education at the time that fosters the most impact.

Burden of CKD

CKD is a disease that not only places a significant burden on the individual, but also plays a large role in national health care costs (Wright Nunes et al., 2011). With proactive measures and knowledge of the disease, the personal and societal burden of CKD can be minimalized.

Personal burden. Patients with CKD commonly have comorbid diseases already affecting their life. With the addition of CKD, patients must engage in further lifestyle modifications in order to improve outcomes. The presence of CKD is a direct risk factor for reduced prognosis for those with diabetes, chronic obstructive disease and acute infections (Eckardt et al., 2013). Furthermore, patients with CKD may face mistreatment or under-diagnosis of disease due to uncertainties of the risks versus benefits of interventions that utilize nephrotoxic medications. Errors in medication dosing have also been noted in this population related to variations in eGFR (Eckardt et al., 2013).

In addition to the physiological effects of CKD, the disease is associated with psychological and emotional burden. Approximately 22% of individuals with CKD have major depression and 37% to 55% report having depressive symptoms; these rates are higher than the general population and in those with other chronic conditions (McKercher et al., 2013). Patients with CKD report poor quality of life because of complications related to the disease, loss of physical functioning or being on some form of RRT (Ayanda, Abiodun, & Ajiboye, 2014; Cruz et al., 2011; McKercher et al., 2013). Patients with more advanced stages of the disease have also

reported symptoms such as worrying, nervousness, irritability and sadness (Almutary, Bonner, & Douglas, 2013). These psychological effects are linked to poorer outcomes and increased likelihood of hospitalization (McKercher et al., 2013).

Societal burden. The reduction in the prevalence of CKD and the healthcare disparities faced by this group is a priority for *Healthy People 2020* (USDHHS, 2013). Though most individuals with CKD may not develop ESRD due to the increased risk of cardiovascular mortality, RRT is a costly procedure and is a large contributor to the economic burden of the disease (Couser et al., 2011). Additionally, individuals with CKD have multiple co-morbidities that drive the cost of health care especially for those who also have diabetes and heart failure. On average a patient with CKD will spend \$1,250 to \$3,000 per month out-of-pocket due to compounding effects requiring constant follow-up with providers, an increased risk of complications and risk for acute kidney injury. CKD also contributes to a decrease in work-force productivity and increases morbidity and mortality rates (Couser et al., 2011). Early detection of CKD allows for a change in management to not only limit the effects of co-morbidities but also decrease the patient's risk for acute kidney injury (Courser et al., 2011).

Significance to Doctorate of Nursing Practice (DNP)

It is imperative to generate new knowledge that can help improve the care and outcomes of individuals with or at high risk for CKD. Knowledge gained from this DNP project will deliver an understanding of the current patient-provider communication practices and will be useful for illustrating gaps in communication that need to be addressed. DNPs are in the ideal position to influence and advocate the need for improving patient-provider communication in the primary care setting. Recent studies show that patients are often unaware of their risk for kidney

disease or current kidney damage; however, if they have been informed, they lack the knowledge to initiate behavioral change (Greer et al., 2011; Mobley, 2009; Wright Nunes, 2013). Without adequate communication of self-management strategies or CKD information, patients at high risk or who have already developed CKD may be limited in their ability to modify their behavior and subsequently lead to poorer outcomes. With early communication of CKD and CKD risk factors, patients are referred earlier to the nephrologist and are also shown to progress slower to ESRD and have a decreased mortality rate (Sakhuja, Hyland, & Simon, 2014).

Evidence-Based Practice

DNPs have the skills and knowledge to critically evaluate and translate evidence into practice. The Institute of Medicine (IOM) issued a statement in 2001 that calls for improvement in the quality and safety of the delivery of health care (IOM, 2001). As part of the action plan, the IOM discussed that clinical decisions must be based on the most current and best available scientific evidence (IOM, 2001). Though current guidelines cannot confirm or deny screening the general population for CKD, DNPs can evaluate the evidence and make an informed clinical decision based on individual patient risk and patient preference (Moyer, 2012). Additionally, implementing evidence-based practice allows the DNP to communicate the most up to date CKD information that is essential for empowering and educating patients at high risk. This DNP project will propose recommendations for communicating CKD information in the primary care setting based on a review of the current literature. Additionally, a communication tool will be developed for future study.

Clinical Management

Aggressive management of individuals with or at high risk for CKD is an essential component for limiting complications and decreasing the need for recurrent hospitalizations (Mobley, 2009). Through effective patient-provider communication and assessment of the patient's readiness to change, DNPs can provide patients with valuable resources and remain proactive in the patient's care. If an individual is aware of the degree of his or her disease, the effects of nephrotoxic substances and the benefits of dietary and lifestyle modifications, this may help limit the effects of the disease (Greer et al., 2011; Hall, Rodriguez, Boyko, Chertow, & O'Hare, 2009; Mobley, 2009; Wright Nunes, 2011; Wright Nunes, 2013). As a clinical leader, DNPs in the primary care setting can make the greatest impact prior to the development of or in the early stages of CKD. This can be done by contributing to the improvement of patient-provider communication through policy change and patient advocacy.

Significance to Society

The burden of CKD increases as the degree of illness progresses to ESRD (Haynes & Winearls, 2010; Matteson & Russell, 2010; USRDS, 2013). With ineffective or limited patient-provider communication patients are placed at a disadvantage (Mobley, 2009; Wright Nunes, 2011). This may also contribute to the increasing prevalence of CKD (Mobley, 2009; Wright Nunes, 2011). Many studies define CKD as a global epidemic due to its contribution to poor patient outcomes as well as the extraneous health care costs associated with treatment (Ayanda, Abiodun, & Ajiboye, 2014; Couser et al., 2011; McKercher et al., 2013; Wright Nunes, 2011). When CKD progresses it costs approximately \$70,000 a year to sustain an individual on dialysis (Mobley, 2009). Thereby improving patient-provider communication prior to or in the early

stages of CKD can change the prevalence and economic expectations for the future. This DNP project will provide a critical analysis and evaluation of the current patient-provider communication practices and will aid in highlighting the implications of poor communication.

Patient-Provider Communication Framework and Trans-Theoretical Model of Change

Patient-provider communication is an essential component of the management and treatment of individuals with or at high risk for CKD. The purpose of this DNP project is to critically synthesize and evaluate patient-provider communication practices in the primary care setting. Feldman-Stewart, Brundage and Tishelman's (2005) Patient-Professional Communication framework and the Trans-theoretical Model (TTM) will be utilized in guiding research for this DNP project. Though the Patient-Professional Communication framework was specifically developed for cancer patients, the components and purpose of the framework is applicable to the CKD population (Feldman-Stewart et al., 2005). This communication framework was formulated in order to understand the communication process and aid in guiding the development of interventions to improve the process (Feldman-Stewart et al., 2005). In addition to understanding the components of communication, the effects of patients' readiness in the acceptance and understanding of interventions is just as relevant; this concept is addressed within the TTM. The central construct of the TTM is the stages of change and can have a direct effect on the success of behavioral change interventions (Teng, Yen, Fetzer, Sung, & Hung, 2013). A more in-depth discussion of Feldman-Stewart et al.'s (2005) framework and TTM is included in Chapter 2.

Summary

Despite improvements in the recognition and diagnosis of CKD in the primary care setting, there is still a significant gap in preventing or prolonging the progression of disease (USRDS, 2013). Early referral to a nephrologist as well as early interventions for those at high risk for CKD is also lagging (Shahinian et al., 2013; USRDS, 2013). The increasing prevalence of the disease may be attributed to the lack of or poor patient-provider communication of CKD in the primary care setting. Through a critical synthesis and evaluation of patient-provider communication practices, this DNP project will shed light on implications and effects of patient-provider communication as well as develop a communication tool to improve the effectiveness of patient-provider communication. The following chapter will discuss the conceptual and theoretical framework utilized for this DNP project.

CHAPTER II: CONCEPTUAL FRAMEWORKS

This chapter will include a discussion of the conceptual frameworks chosen to guide the research and development of this DNP project. As previously discussed improvement of future health risk in patients with or at high risk for developing CKD is dependent on significant lifestyle modifications, many of which are learned through discussions with various health care providers (Lopez-Vargas et al., 2014). The concurrent use of a communication framework and the TTM stages of change helped identify strategies to improve patient-provider communication and the likelihood of achieving desired outcomes. Without knowledge and integration of both the communication process and components that influence behavioral change, the communication tool developed from the systematic review may not be as effective. Communication points that are developed based on the patient's stage of change are likely to be more accepted by the patient and may benefit both the provider and patient in meeting shared health goals.

Patient-Professional Communication Framework

One of the conceptual frameworks used for this DNP project is Feldman-Stewart, Brundage and Tishelman's (2005) conceptual framework for patient-professional communication. The use of a conceptual framework provided guidance for organizing and summarizing research in addition to assessing the communication process and developing interventions and suggestions to improve communication (Feldman-Stewart et al., 2005). This framework was chosen due to its simplicity and applicability to CKD-related communication. Though this framework was developed within the cancer context, its components are easily translated to apply to CKD-related communication.

Effective patient-provider communication is important for CKD management because a large majority of care is dependent on education and patient participation (Mobley, 2009; Wright Nunes, 2011; Wright Nunes, 2013). Patients often rely on the expertise and guidance from providers in order to engage in self-management behavior. If patient-provider communication is poor or lacking, patients may not understand the health consequences of their actions and their future risk for morbidity and mortality due to CKD (Mobley, 2009).

Framework Components

The framework was developed to show the one-to-one in person communication process between the provider and patient. This communication serves to address the goals of each participant and can be influenced by both internal and external factors. Feldman-Stewart et al.'s (2005) framework consists of four components. These include: goals, patient's beliefs and values, communication process, and environment. The conceptual framework is presented in Figure 1.

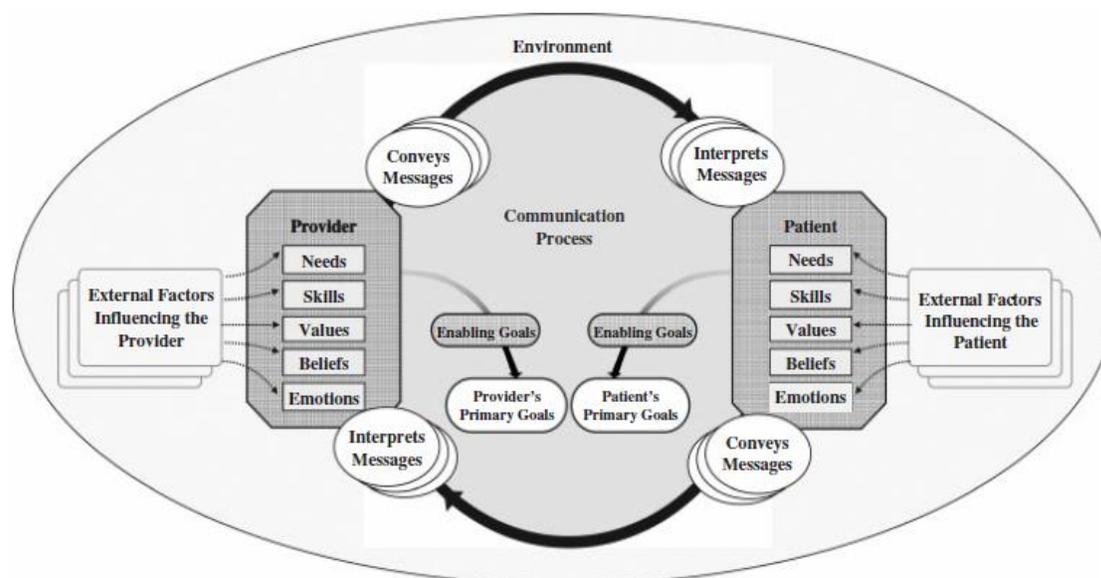


FIGURE 1. Conceptual Framework for Patient-Professional Communication.

(Note. From “A conceptual framework for patient-professional communication: An application to the cancer context,” by D. Feldman-Stewart, M.D. Brundage and C. Tishelman, 2005, *Psycho-Oncology*, 14, p. 803. Copyright 2005 by John Wiley & Sons, Ltd. Reprinted with permission.)

Goals

The purpose of communication is to address the goals of the participants. In the health-care context, the participants include the provider and the patient. The goal is defined as “the objective of the participant’s communication effort, meaning that each encounter has particular goals” and is an expression of the participant’s needs (Feldman-Stewart et al., 2005, p. 803). For example, a goal for a patient may be to understand his or her health condition while the provider’s goal may be to deliver effective care. Additionally, if the participant is unable to express his or her goals, the communication process can serve as a guide to help articulate and/or discover new goals (Feldman-Stewart et al., 2005). In contrast, the communication process may also present conflicting goals in which negotiation is needed to determine the goals that will be discussed during the encounter (Feldman-Stewart et al., 2005).

Primary goals. Primary goals prompt the communication process and can be described as the reason for communicating with the provider. To evaluate the success of the encounter, it is essential to conceptualize these goals. According to Feldman-Stewart et al. (2005), successful communication does not necessarily mean that the primary goals are fully realized but rather the encounter helps the participant work towards his or her goals. For example, the primary goal of the patient may be to better understand their risk for CKD and the provider may have an equivalent goal of providing information to the patient. The provider may disclose all of the information in the first encounter or may feel that additional encounters may be needed to fully inform the patient (Feldman-Stewart et al., 2005). Though the primary goal is not fully achieved, the encounter will help the participant move a step closer to achieve his or her personal goal.

Secondary goals. Secondary goals are enabling actions that help the participant achieve the primary goals. Furthermore, these goals may serve one or more of the primary goals. An example of this is identifying the patient's treatment goals and desire to engage in lifestyle modifications. Having this secondary goal as a provider may help achieve the primary goal of developing a treatment plan. Conversely, a patient may have the desire to develop a trusting relationship with the provider which will help the patient achieve his or her primary goal of making treatment decisions (Feldman-Stewart et al., 2005).

Participant Attributes

The communication process is directly influenced by the participant's attributes. These include key factors such as needs, beliefs, values, skills and emotions. Additionally, the participant's attributes contribute to the development and interpretation of the messages conveyed and received (Feldman-Stewart et al., 2005).

Needs. Needs are conceptualized as the underlying motivation for the encounter; why did the patient initiate contact with the provider? These can be categorized as intrinsic and secondary needs of human functioning, which are related to basic physiology and safety, social, psychological, and self-actualization needs. Some examples of these include food, security, affiliation, self-respect, autonomy, and need for truth (Feldman-Stewart et al., 2005). In communicating with the CKD patient, it is pertinent that the provider acknowledges these needs in order to improve the success of the encounter.

Beliefs. Beliefs are a representation of the participant's understanding of his or her world and what he or she thinks to be fact. These can be influenced and changed through interactions as well as through feedback both internally and externally from the other participant (Feldman-Stewart et al., 2005). In the CKD context, this may include what the disease means to the participant as well as his or her learned coping strategies. The communication process may help identify gaps in the patient's knowledge and facilitate education in relation to the patient's knowledge deficits.

Values. The participant's values are the principles or standards that the participant lives by. In combination with beliefs these may produce the participant's attitudes and are central to the participant's daily functioning (Feldman-Stewart et al., 2005; Feldman-Stewart & Brundage, 2009).

Skills. Skills are what help the participant accomplish his or her goals and are integral to the participant's ability to communicate (Feldman-Stewart et al., 2005; Feldman-Stewart & Brundage, 2009). Many skills are required in order to convey verbal and non-verbal messages and differ from the skills that help to understand and interpret the messages received. These

skills are developed slowly over time and can also change during a particular encounter based on internal and external feedback. Internally, the participant may recognize that the information presented was not conveyed well or externally, the other participant may have a look of confusion (Feldman-Stewart et al., 2005).

Emotions. Most emotions are communicated non-verbally and are described as both negative and positive. These may be transient emotions -- emotions that change depending on the communication -- or stable emotion such as the participant's temperament or traits (Eysenek & Eysenek, 1985 as cited in Feldman-Stewart et al., 2005). Examples of emotions are joy, fear and sadness (Feldman-Stewart et al., 2005). Through the course of CKD, patients may experience a variety of emotions. These can range from shock due to the initial diagnosis to joy after meeting health goals.

Communication Process

In Figure 1, Feldman-Stewart et al. (2005) illustrate that the development and interpretation of messages are the central actions of the communication process. Conveyed messages are considered either active or passive while interpreted messages are composed of content and emotion. Moreover, messages can be conveyed intentionally or unintentionally and multiple messages can be delivered and received at one time (Feldman-Stewart et al., 2005).

Conveyed messages. Active messages are verbal or non-verbal meaning they are either expressed using words or through tone of voice, facial expressions and body language respectively. Passive messages lack action but can intentionally or unintentionally relay a message. An example of this is the use of silence or a lack of response when one is expected. Participants in the communication process can interpret silence as being negative or positive

(Feldman-Stewart et al., 2005). For example, patients may remain silent after being given information about their disease because they understand the information or they may be overwhelmed with the information.

Interpreted messages. Comprehension of the conveyed messages includes an interpretation of either content or emotion. Content and emotion can be conveyed in both active and passive messages. For example, Feldman-Stewart et al. (2005) describe verbal messages as usually containing content. However, they can be used to describe emotion such as the patient explaining that he or she is afraid of the CKD diagnosis or they do not understand what actions to take to prevent or slow the progression of the disease. Additionally, passive messages can convey content if the provider interprets the patient's silence as the patient understanding the information provided (Feldman-Stewart et al., 2005).

Environment

The environment is described as the influencing factors that occur outside of the communication process that affect the participants' attributes. These include: social, cultural, legal, and physical factors. Some may affect each participant individually while others may affect all involved in the communication process. According to Feldman-Stewart et al. (2005), influencing factors can be new or learned information that changes the participant's previous beliefs or can be longstanding such as the participant's cultural beliefs that influence his or her values.

Trans-Theoretical Model of Change

Effective chronic disease management and promotion of healthy lifestyle changes requires a combination of the patient's perception of his or her disease as well as effective

communication between the provider and patient (Fort et al., 2013). Utilizing Feldman-Stewart et al.'s (2005) communication framework in conjunction with the TTM stages of change will provide a better understanding of the components and barriers of communication and may aid the provider in shaping communication in a way the patient is ready to hear, i.e. provide messages appropriate to the patient's stage of change.

Stages of Change and Communication

The TTM posits that patients are motivated to make behavioral changes through a series of cognitive processes that affect the individual's decision making (Prochaska & DiClemente, 1983; Teng et al., 2013). The stages of change which is the framework's central concept, has been the focus for many health promotion studies. It is thought that patients go through a series of stages—though not necessarily linear—while engaging in behavioral changes (Fort et al., 2013). Identifying the patient's stage of change while developing a plan of care can improve patient-provider communication and help motivate patients to progress to more active stages of change such as action and maintenance (Fort et al., 2013). Additionally, studies show that increased awareness of CKD alone is not enough to influence patients to engage in lifestyle modifications (Teng et al., 2013). This further emphasizes the importance of identifying communication strategies that can successfully influence behavioral modifications in order to improve risk of the development or progression of CKD.

The TTM stages of change have been cited in various studies relating to chronic illness management; in recent years, its utilization has increased in studies addressing behavioral lifestyle modifications among individuals with CKD (Garcia-Llana, Remor, del Peso, Celadilla, & Selgas, 2013; Murali et al., 2012; Teng et al., 2013). Moreover, studies suggest that the

concepts of the TTM stages of change can be easily integrated into patient-provider communication and its applicability reaches a far range of diverse populations (Greene et al., 2013; Nigg et al., 2011). The stages of change include: pre-contemplation, contemplation, preparation, action and maintenance (Prochaska & DiClemente, 1983), which will be discussed below.

Pre-Contemplation

In the pre-contemplation stage, patients do not intend to take action within the next six months, lack awareness of an underlying disease or may avoid reading, talking or thinking about their disease or high-risk behaviors (Prochaska & DiClemente, 1983; Velicer et al., 2000). These actions may be attributed to a lack of knowledge of the consequences of their behaviors or patients have become unmotivated due to multiple failed attempts to change (Velicer et al., 2000). Within this stage, patients may identify with statements such as “I currently do not follow a healthy diet and do not engage in regular physical activity. I also do not plan to do so in the next six months” (adapted from Teng et al., 2013). In order to help patients move from the pre-contemplation stage to contemplation, messages may be tailored to include a discussion of consequences due to poor diet and exercise, identify reasons why the patient is not engaging in dietary and lifestyle modifications and provide information to help the patient make informed decisions relating to his or her care. The goal for this stage is to increase the patient’s awareness for the need to change (Teng et al., 2013).

Contemplation

The contemplation stage is where the patient has intentions to change his or her behavior in the next six months but is still weighing the pros and cons of the behavioral change.

Furthermore, these patients are not ready to participate in activities that expect immediate action (Velicer et al., 2000). A patient may tell the provider that he or she is not currently following a healthy lifestyle regimen (dietary modifications, medication adherence and exercise) but has been thinking of making a change within the next six months. At this point, interventions should be focused on increasing the patient's confidence in his or her ability to make a change. Additional discussions should include the benefits and barriers to lifestyle modifications, setting individual goals and identifying strategies to achieve those goals (Teng et al., 2013).

Preparation

Patients who are in the preparation stage may make statements such as "I do not currently follow a healthy lifestyle regimen, but I have plans to do so in the next month" (adapted from Teng et al., 2013; Velicer et al., 2000). These patients may benefit from action-oriented educational programs and are committed to engage in change (Nigg et al., 2011; Velicer et al., 2000). Additionally, patient-provider communication strategies may include discussing ways to overcome perceived barriers, praise the patient for engaging in healthy lifestyle choices and identify the patient's needs to continue the desired behaviors (Teng et al., 2013).

Action

In the action stage, patients have made a recent change in their behavior within the last six months (Velicer et al., 2000). PCPs may ask patients if they feel they are meeting their goals and praise him or her for adhering to lifestyle changes that will aid in preventing or slowing the progression of the disease. Patients should receive positive reinforcement to maintain the patient's confidence in their ability to continue the change (Teng et al., 2013).

Maintenance

Patients in the maintenance stage are less likely to relapse and are making strides to continue the lifestyle change. Furthermore, patients are confident in their abilities and may last between six months to five years in this stage (Velicer et al., 2000). The goal for the primary care provider in this stage is to help the patient develop strategies to prevent relapse. Communication strategies may include encouraging the patient to develop new goals, re-emphasize the importance of following a healthy kidney regimen and identifying areas in which the patient may need support (Teng et al., 2013). It is also important to note that patients may regress and progress within the stages differently (Velicer et al., 2000). Therefore, it is essential as the primary care provider to individualize communication strategies in order to increase the likelihood of desired outcomes.

Integration of Conceptual Frameworks

In order to prevent the development or slow the progression of CKD, this requires significant self-management behavior including the management of co-morbidities, improvement in dietary habits, exercise and adherence to medication regimens (Walker et al., 2013). Studies also show that the patient's perception of the disease and effective communication are central to the promotion of lifestyle changes and managing chronic illnesses (Fort et al., 2013). The utilization of both the TTM stages of change and communication framework is essential for the realization of desired goals.

Although all of the components of the communication framework are essential for effective communication, a more specific target for this DNP project is the communication goals. This is one of the key components of Feldman-Stewart et al.'s (2005) communication framework

and is the main purpose of the patient-provider interaction. With the integration of the TTM, providers can impart information to the patient in a way that would be realistically accepted based on the patient's readiness to change. Additionally, the TTM can provide a guideline for understanding the potential patient goals at each stage of change. For example, in the pre-contemplation stage, the patient may not be aware of their risk for disease or have no desire to change. Their goal during the patient-provider interaction would likely have no relation to CKD or managing their risk factors. Therefore, the provider would need to change their communication points to address the patient's risk and/or understand the individual's perceived barriers to change (Teng et al., 2013). If interventions or communications points are not congruent to the patient's stage of change, there can be resistance or treatment failure as the patient may not engage in the suggested interventions (Teng et al., 2013). Therefore, by establishing communication goals that align with the patient's stage of change, this will aid in the understanding self-management behavior that will prevent or slow the progression of CKD.

Summary

This chapter provided an overview of the conceptual frameworks utilized for guiding the research and development of this DNP project. Feldman-Stewart et al.'s (2005) patient-professional communication framework discusses communication in terms of participant goals, participant beliefs and values, the communication process and the environment. In combination, each component can affect the development and interpretation of messages and can help highlight success and failure of communication. The TTM stages of change further integrates strategies to improve communication by emphasizing the importance of addressing the individual readiness to accept change (Prochaska & DiClemente, 1983; Teng et al., 2013). These

frameworks provided guidance in identifying communication strategies of self-management behavior for those with CKD and high risk populations. Additionally, the integration of both frameworks in a communication tool will likely be useful in improving communication, patient outcomes and self-management behavior. The proposed communication tool is intended for future study and use in the primary care setting. Chapter 3 provides an explanation of the methods used to develop the communication tool.

CHAPTER III: METHODS

A systematic review and analysis of the current literature relating to the communication processes used to influence self-management and behavioral change in the primary care setting was conducted. The initial search included all communication processes influencing self-management behavior or behavioral change among the CKD population. Communication processes that influence self-management and behavioral change for patients at high risk for developing CKD were also included in order to provide a larger database of information. The targeted high-risk population are those with hypertension and/or diabetes. This DNP project was reviewed by the University of Arizona IRB and determined that no human subjects were used, therefore requiring no oversight (Appendix F).

The literature review followed the method guidelines developed by the Cochrane Collaboration (Green et al., 2011). These guidelines provide a standardized approach for conducting a systematic review (Furlan, Pennick, Bombardier, & van Tulder, 2009). In addition to this, the Johns Hopkins Nursing Evidence Based Practice (JHNEBP) Research Evidence appraisal tool was used in order to evaluate the evidence level and quality (Newhouse, Dearholt, Poe, Pugh, & White, 2007). Following the review, recurring themes in communication processes of the most successful interventions were identified. These themes aided in the development of a communication tool. The purpose of identifying themes was to improve the effectiveness of patient-provider communication of self-management behavior that can aid in preventing or slowing the progression of CKD.

Cochrane Method for Systematic Review

In 2001, the IOM issued a statement addressing the large gap in current nursing knowledge and the provision of quality health care. In order to improve this, the IOM discussed the importance of engaging in evidence-based practice as well as increasing the availability of trustworthy systematic syntheses of current evidence (Mallory, 2010). The Cochrane Handbook for Systematic Review is useful for planning, conducting and evaluating systematic reviews. Furthermore, it provides for a standardized approach that helps improve the effectiveness and quality of the reviews (Furlan et al., 2009). The Cochrane method is a seven-step approach that includes review objective, literature search, data extraction, assessing risk bias, data analysis, summary and interpretation of results (Green et al., 2011). In combination with Feldman-Stewart et al.'s (2005) Patient-Professional Communication framework and the Transtheoretical Model of Change, the Cochrane Method for Systematic Review aided in the identification of gaps in the current literature and provided insight for the development of a communication tool.

Review Objective

The first step of the Cochrane Method for Systematic Review is to identify the topic and to develop the objective and purpose of the review (O'Conner, Green, & Higgins, 2011). The objective of the systematic review is to identify existing strategies and practices of patient-provider communication of self-management and behavioral change strategies among patients with or at high risk for developing CKD in the primary care setting. As previously mentioned, there is a lack of research specifically aimed at improving patient-provider communication among this population. The research question developed for this DNP project is: What are the current communication practices in primary care or outpatient settings regarding self-

management and behavioral change and their effectiveness in preventing the development of CKD or rapid progression to ESRD? PCPs are in the best position to communicate CKD risk and strategies for self-management behavior in the early stages when intervention has the largest impact on slowing the development or progression to ESRD (Walker et al., 2013). Examples of treatment approaches to slow the development of CKD or progression to ESRD includes good blood pressure and blood sugar control (Devraj & Wallace, 2013).

Literature Search

The second step of the Cochrane Method for Systematic Review is the literature search (Lefebvre, Manheimer, & Glanville, 2011). It is essential to include as much evidence as possible in the literature search in order to properly assess the research question in review (Furlan et al., 2009). Therefore, search variables should be developed based on the research question and inclusion criteria must be established. Additionally, detailed documentation for the search strategy is essential to ensure that searches of all databases can be reproducible. The detailed search strategy used for each of the databases searched is included in Chapter 4.

A systematic review of the current literature was completed including gray literature sources. The search aimed to identify all studies evaluating or developing interventions related to communication of self-management or behavioral change among patients with or at high risk for developing CKD in the primary care setting. Databases utilized for the literature review included PubMed, Cochrane Database of Systematic Reviews, Education Resource Information Center (ERIC) and Cumulative Index to Nursing and Allied Health Literature (CINAHL), Embase and PsychInfo. Initial search terms included patient-provider communication combined with chronic kidney disease. Additional search terms included a combination of patient-provider

communication, communication strategies, self-management strategies, self-efficacy, stages of change, transtheoretical model of change and CKD, diabetes, hypertension. Inclusion criteria included: (a) humans, adults age 18 years and older, (b) primary research studies, systematic and literature reviews, (c) focus on communication of self-management or behavioral change strategies among patients with CKD, hypertension or diabetes (d) Main outcomes included improving self-management or behavioral change and/or improving patient outcomes (i.e. blood sugar and blood pressure control) (e) Availability of full-text online or by request. Ancestry and descendency approaches were used in order to ensure completeness of review.

Data Extraction

Data extraction is one of the most important components of a systematic review of the literature. Proper extraction of information will lead to a better comparison of studies and understanding of knowledge gaps in the current literature. This systematic review followed a combination of guidelines for data extraction from the Cochrane handbook (Higgins & Deeks, 2011) and Polit and Beck (2012). The Cochrane handbook emphasizes that data extraction should follow a standardized form so that all necessary data are collected (Higgins & Deeks, 2011). Some of the components of the data extraction tool included source, type of study, setting, study design, participant characteristics, methods/measures, outcomes, effect sizes, key conclusions, strengths and weaknesses (Higgins & Deeks, 2011; Polit & Beck, 2012). The data extraction tool can be found in Appendix A. Extracted data were used to critique the studies and some of the components of the data extraction were translated into table format for the summary of results, which can be found in Appendix B.

Assessing Risk of Bias

The development of the communication tool was dependent on the validity of the data and results of the studies included in the systematic review. The Cochrane Method suggests that all studies be tested for bias utilizing a standardized format. Current empirical evidence supports the need for assessing risk bias (Higgins, Altman, & Sterne, 2011). The Cochrane's assessment of bias includes an evaluation of five domains: selection, performance, attrition, detection and reporting bias. Within the tool, there are specific supportive judgments that need to be made in order to assign a level of risk for each domain. A low level of risk is where a plausible bias is unlikely to seriously affect the results where a high level of risk is where a plausible bias can seriously weaken the confidence of the study's results (Higgins, Altman, & Sterne, 2011). If a plausible bias causes doubt in the results, this can be identified as unclear risk of bias (Higgins, Altman, & Sterne, 2011). Any domain identified as possible risk for bias will be identified in the summary of findings table (Appendix B). Table 3 provides the various domains of bias and questions to help evaluate risk bias.

TABLE 3. *Cochrane Risk Bias Assessment Tool (Higgins, Altman, & Sterne, 2011).*

Domain	Evidence to Support Judgement
Selection Bias- Random sequence generation	Method used to generate allocation sequence. Can comparable groups be produced?
Selection Bias- Allocation concealment	Method used to conceal the allocation sequence. Could the intervention allocations have been foreseen in advance of, or during, enrolment?
Performance Bias- Blinding of participants and personnel	Measures used to blind study participants and personnel from knowledge of intervention a participant received. Was the intended blinding effective?
Detection Bias- Blinding of outcome assessment	Measures used to blind outcome assessors from knowledge of intervention a participant received. Was the intended blinding effective?
Attrition Bias- Incomplete outcome data	Completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. Were attrition and exclusions reported? Were the numbers in each intervention group (compared with total randomized participants) and reasons for attrition/exclusions reported? Were there any re-inclusions in analyses performed?
Reporting Bias- Selective reporting	How was the possibility of selective outcome reporting examined and what was found?
Other Bias	Are there other concerns not mentioned within the risk bias assessment?

Data Analysis

The next step of the Cochrane method is a meta-analysis. For the purpose of this DNP project, a meta-analysis was not completed due to variability in outcome measures.

Presentation of Results

The sixth step of the Cochrane method is the presentation of results in a ‘summary of findings table.’ The data identified in the literature search were translated into table format. The ‘summary of findings table’ (Appendix B) was developed from the extracted data from the data extraction. Some key results included in the table were source, type of study, setting, study design, participant characteristics, measures/methods, outcomes, key conclusions, risk bias and

evidence rating (Higgins & Deeks, 2011; Polit & Beck, 2012). A clear, logical presentation of the results aided in the identification of emerging themes and gaps in the current literature.

Interpreting Results

The final step of the Cochrane method for systematic reviews is the interpretation of the results. This includes a discussion of the outcomes, including adverse outcomes and evaluation of the level of strength and quality of the evidence (Schünemann et al., 2011b). The JHNEBP model was used to rate the strength and quality of evidence accepted for the systematic review (Newhouse et al., 2007). Evidence ratings range from strong evidence (Level I) and high quality (A) to lower strength evidence (Level III) and less quality (C). The strongest level, Level I evidence, is derived from experimental study/randomized controlled trials (RCT) or meta-analysis while the lowest level, Level III is derived from a non-experimental study, qualitative study or meta-synthesis. Table 4 provides an overview of the JHNEBP rating scheme for strength of evidence while Table 5 provides a list of criteria for rating the quality of the evidence. Additionally, the JHNEBP Research Evidence Appraisal tool was used as a guide to ensure all necessary points were evaluated in each study to accurately determine the level and quality of evidence (Figures 2 and 3) (Newhouse et al., 2007). By doing so, this ensured that the best available evidence was utilized for developing the communication tool.

TABLE 4. *JHNEBP Strength of Evidence Rating Scheme (Newhouse et al., 2007).*

Level	Type of Evidence
I	Experimental study/RCT or meta-analysis of RCTs
II	Quasi-experimental study
III	Non-experimental study, qualitative study, or meta-synthesis

TABLE 5. *JHNEBP Quality of Evidence Rating Scheme (Newhouse et al., 2007).*

Grade	Research Evidence Criteria
High (A)	Consistent results. Sufficient sample, adequate control, definite conclusions. Recommendations consistent and based on extensive literature review with reference to scientific evidence
Good (B)	Reasonably consistent results. Sufficient sample, some control, fairly definitive conclusions. Reasonably consistent recommendations based on fairly comprehensive literature review with some reference to scientific evidence
Low/Major Flaw (C)	Little evidence with inconsistent results. Insufficient sample size and no conclusions

JHNEBP Research Evidence Appraisal

Evidence Level: _____

ARTICLE TITLE:				NUMBER:	
AUTHOR(S):				DATE:	
JOURNAL:					
SETTING:			SAMPLE (COMPOSITION/SIZE)		
<input type="checkbox"/> Experimental	<input type="checkbox"/> Meta-analysis	<input type="checkbox"/> Quasi-experimental	<input type="checkbox"/> Non-experimental	<input type="checkbox"/> Qualitative	<input type="checkbox"/> Meta-synthesis
Does this study apply to my patient population?				<input type="checkbox"/> Yes	<input type="checkbox"/> No
If the answer is No, STOP here (unless there are similar characteristics).					
Strength of Study Design					
<ul style="list-style-type: none"> • Was sample size adequate and appropriate? • Were study participants randomized? • Was there an intervention? • Was there a control group? • If there was more than one group, were groups equally treated, except for the intervention? • Was there adequate description of the data collection methods 				<input type="checkbox"/> Yes	<input type="checkbox"/> No
				<input type="checkbox"/> Yes	<input type="checkbox"/> No
				<input type="checkbox"/> Yes	<input type="checkbox"/> No
				<input type="checkbox"/> Yes	<input type="checkbox"/> No
				<input type="checkbox"/> Yes	<input type="checkbox"/> No
				<input type="checkbox"/> Yes	<input type="checkbox"/> No
Study Results					
<ul style="list-style-type: none"> • Were results clearly presented? • Was an interpretation/analysis provided? 				<input type="checkbox"/> Yes	<input type="checkbox"/> No
				<input type="checkbox"/> Yes	<input type="checkbox"/> No
Study Conclusions					
<ul style="list-style-type: none"> • Were conclusions based on clearly presented results? • Were study limitations identified and discussed? 				<input type="checkbox"/> Yes	<input type="checkbox"/> No
				<input type="checkbox"/> Yes	<input type="checkbox"/> No
PERTINENT STUDY FINDINGS AND RECOMMENDATIONS					
Will the results help me in caring for my patients?				<input type="checkbox"/> Yes	<input type="checkbox"/> No
Evidence Rating (scales on back)					
Strength of Evidence Rating					
Quality Rating (check one)					
<input type="checkbox"/> High (A)		<input type="checkbox"/> Good (B)		<input type="checkbox"/> Low/major flaws(C)	

FIGURE 2. JHNEBP Research Evidence Appraisal Tool (Front).

(Note. From Newhouse, R.P., Dearholt, S.L., Poe, S.S., Pugh, L.C., & White, K.M. (2007). *Johns Hopkins Nursing Evidence-Based Practice: Model and Guidelines*. Indianapolis: Sigma Theta Tau International. Copyright 2007 by The Johns Hopkins Hospital/The Johns Hopkins University. Reprinted with permission.)

STRENGTH OF EVIDENCE**LEVEL 1 (HIGHEST)****EXPERIMENTAL STUDY (RANDOMIZED CONTROLLED TRIAL OR RCT)**

- Study participants (subjects) are randomly assigned to either a treatment (TX) or control (non-treatment) group.
- May be:
 - Blind: neither subject nor investigator knows which TX subject is receiving.
 - Double-blind: neither subject nor investigator knows which TX subject is receiving.
 - Non-blind: both subject and investigator know which TX subject is receiving; used when it is felt that the knowledge of treatment is unimportant.

META-ANALYSIS OF RCTS

- Quantitatively synthesizes and analyzes results of multiple primary studies addressing a similar research question
- Statistically pools results from independent but combinable studies
- Summary statistic (effect size) is expressed in terms of direction (positive, negative, or zero) and magnitude (high, medium, small)

LEVEL 2**QUASI-EXPERIMENTAL STUDY**

- Always includes manipulation of an independent variable
- Lacks either random assignment or control group.
- Findings must be considered in light of threats to validity (particularly selection)

LEVEL 3**NON-EXPERIMENTAL STUDY**

- No manipulation of the independent variable.
- Can be descriptive, comparative, or relational.
- Often uses secondary data.
- Findings must be considered in light of threats to validity (particularly selection, lack of severity or co-morbidity adjustment).

QUALITATIVE STUDY

- Explorative in nature, such as interviews, observations, or focus groups.
- Starting point for studies of questions for which little research currently exists.
- Sample sizes are usually small and study results are used to design stronger studies that are more objective and quantifiable.

META-SYNTHESIS

- Research technique that critically analyzes and synthesizes findings from qualitative research
- Identifies key concepts and metaphors and determines their relationships to each other
- Aim is not to produce a summary statistic, but rather to interpret and translate findings

QUALITY RATING (SCIENTIFIC EVIDENCE)

- A **High quality:** consistent results, sufficient sample size, adequate control, and definitive conclusions; consistent recommendations based on extensive literature review that includes thoughtful reference to scientific evidence.
- B **Good quality:** reasonably consistent results, sufficient sample size, some control, and fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence
- C **Low quality or major flaws:** little evidence with inconsistent results, insufficient sample size, conclusions cannot be drawn.

FIGURE 3. JHNEBP Research Evidence Appraisal Tool (Back).

(Note. From Newhouse, R.P., Dearholt, S.L., Poe, S.S., Pugh, L.C., & White, K.M. (2007). *John Hopkins Nursing Evidence-Based Practice: Model and Guidelines*. Indianapolis: Sigma Theta Tau International. Copyright 2007 by The Johns Hopkins Hospital/The Johns Hopkins University. Reprinted with permission.)

Communication Tool

The final step of this DNP project was to propose a communication tool to be utilized by PCPs in order to enhance the patient-provider communication of CKD related information and self-management behavior. With the proposed communication tool this author aims to provide a guide for discussion points to include in each patient encounter among patients with newly diagnosed CKD or at high risk for the disease. Intervention in the early stages or prior to the development of CKD can significantly improve future outcomes (Walker et al., 2013). Therefore, this population will most benefit in the improvement of patient-provider communication of self-management or behavioral change strategies.

The communication tool was developed and categorized based on Prochaska and DiClemente's (1983) stages of change. The questions and recommended interventions in each stage category were framed to relate to those with CKD while taking into consideration the components of the communication framework more specifically establishing and addressing the goals of the communication. According to Feldman-Stewart et al. (2005) the purpose of communication is to address the goals of the participants. If goals are conflicting this may hinder the effectiveness of the communication and subsequently lead to less desirable outcomes. The communication tool is intended to be used once the provider has identified the individual's stage of change. Therefore, a supplemental questionnaire to be completed by the patient prior to the encounter will be provided in order to aid in identifying the patient's stage of change (SOC). The questionnaire will include specific action criterion constructed based on the TTM (Prochaska & DiClemente, 1983).

If the patient is identified to be in the precontemplation stage the goal at this stage for the patient may be simply to be seen by the provider for his or her annual check-up while the provider's goal is to get the patient to engage in lifestyle changes. A proposed communication point would be to identify what the patient knows about their disease and possible barriers hindering the patient's desire or ability to engage in lifestyle changes. By developing a communication tool based on the stages of change, barriers of communication may be eliminated helping the patient and provider negotiate goals in order to prevent or slow the progression of CKD. Furthermore, if the interventions or discussion points do not meet the patient's stage of change, the goals of the provider may never be met. Ultimately, the patient's desire to change is the cornerstone to desired outcomes.

Summary

The methods section discussed the standardized approach employed in conducting the systematic review. The systematic review followed the Cochrane Handbook which includes a seven-step approach: review objective, literature search, data extraction, assessing risk bias, data analysis, presentation and interpretation of results. The level of strength and quality of evidence were evaluated using the JHNEBP Model (Newhouse et al., 2007). Following the review, recurrent themes of the most successful self-management interventions were analyzed to identify communication processes for developing a communication tool to improve patient-provider communication of self-management or behavioral change interventions among patients with or at high risk for developing CKD. As the prevalence for CKD increases in the U.S. population to upward of 29 million and with millions more at risk, it is important to educate and motivate

patients before developing CKD or in the early stages (NKF, 2015). ESRD is a life-altering disease and can be prolonged or prevented with early intervention (Walker et al., 2013).

CHAPTER IV: RESULTS

The detailed search strategy and results of the systematic review are presented in this chapter. As previously discussed, the systemic review was carried out following the method guidelines developed by the Cochrane Collaboration (Green et al., 2011). The review attempted to identify all of the key published articles. The databases searched included: PubMed, Cochrane Database of Systematic Reviews, CINAHL, PsychInfo, EMBASE and ERIC. A search of the grey literature was also conducted to ensure completeness of review. The searches were conducted between December and January 2016. Following the review is a proposed communication tool that was developed as a strategy to enhance patient-provider communication in the primary care setting.

Search Strategy and Summary

The search aimed to identify all studies related to the communication of self-management and/or behavioral change interventions in the primary care or outpatient setting between providers and patients with or at high risk for developing CKD. Patient-provider communication was defined as any verbal or written exchange of CKD-related information between the patient and provider. Communication in the context of individual consultation, group education, electronic communication and telephone consultation are just a few of the avenues for exchange included in the review. The initial search was conducted in PubMed using the search terms ‘patient-provider communication’ and ‘chronic kidney disease.’ A total of four studies were identified. Of those, two were accepted after title sifting but were later excluded following abstract review (Tuot et al., 2015; Yank, Tribett, Green, & Pettis, 2015). The first article was excluded because it was a protocol for a future randomized controlled trial (RCT) (Tuot et al.,

2015). The second article, a feasibility study, did not align with the primary outcome measures for the systematic review; the study identified the feasibility of applying the intervention versus identifying its impact on enhancing self-management or behavioral change (Yank et al., 2015). After the initial search a combination of key terms: ‘communication strategies,’ ‘patient-provider communication,’ ‘self-management strategies,’ ‘self-efficacy strategies,’ ‘stages of change,’ ‘transtheoretical model of change’ AND ‘chronic kidney disease,’ ‘hypertension,’ ‘diabetes’ were applied in all six databases. Each database was subjected to at least 22 and up to 24 separate searches. Each key term listed above was combined with the chronic condition using the Boolean phrase ‘AND.’ For example, the first search in CINAHL was ‘communication strategies’ AND ‘chronic kidney disease.’ The key terms were subsequently exhausted for each chronic condition in the order listed above. Once this was completed, the next database was searched. In ERIC and Cochrane databases an initial search using the key terms ‘self-management strategies’ and ‘self-efficacy strategies’ combined with ‘chronic kidney disease,’ ‘diabetes’ and ‘hypertension’ resulted in a limited number of studies. Therefore, the key terms ‘self-management’ and ‘self-efficacy’ combined with each chronic condition were used to broaden the search; these terms were not used in the other four databases. In the other four databases, the key terms ‘self-management’ and ‘self-efficacy’ were too broad. For example, in PubMed ‘self-management’ AND ‘diabetes’ resulted in over 15,000 articles.

A total of 5765 articles were located and subjected to a title and abstract review. Of these, 44 articles were retained for data extraction and 16 articles were eliminated after full-text review. Table 6 includes a statistical overview of the search strategy. A majority of the articles found were duplications and eliminated immediately. Studies were also eliminated by title and abstract

review if the title clearly had no relevance to the research question, did not meet inclusion criteria or included a mixed population of chronic conditions other than CKD, HTN or DM and/or pediatric populations. A total of 28 articles met inclusion criteria. 24 articles were found from the search strategy and four were identified by the gray literature (Appendix C). Inclusion criteria were based upon: (a) age, (b) empiric design, (c) English language, (d) availability of full-text online or requested (e) focused on communication processes of self-management or behavioral interventions and (f) included primary outcomes addressing improvement in self-management or behavioral change and/or improving patient outcomes (i.e., blood sugar or blood pressure control). Of the 16 articles eliminated, two articles were protocols for a future RCT and provided no data for the outcomes measures (Bosworth et al., 2009; Ong, Jassal, Porter, Logan, & Miller, 2013). In five studies, the primary outcome measures focused on predictors of self-management or behavioral change rather than improvement in actual behaviors (Brown, Bartholomew, & Naik, 2007; Johnson et al., 2015; Ryvicker, Feldman, Chiu, & Gerber, 2013; Theunissen, de Ridder, Bensing, & Rutten, 2003; Weirdsma, va Zuil, & van der Bijl, 2011). For example, Ryvicker et al. (2013) tested a behavioral intervention to improve patient activation. Patient activation refers to the patient's knowledge, skills, ability and willingness to engage in self-care behaviors. However, the primary outcome was focused on the improvement of patient activation scores; the study did not identify whether behaviors were actually changed due to the intervention (Ryvicker et al., 2013). Another two articles did not provide adequate detail of the intervention therefore limiting the ability to draw definitive conclusions related to a communication strategy (Clark, Hampson, Avery, & Simpson, 2004; Karupaiah, Wong, Chinna, Arasu, & Siew Swee Chee, 2015). The remaining articles included adolescents (Attridge,

Creamer, Ramsden, Cannings-John, & Hawthorne, 2014), interventions were not conducted between patient and provider (Blakeman et al., 2014), included transplant and ESRD populations (Li et al., 2011), interventions did not specifically target improvement in self-management or patient outcomes for slowing progression of CKD (Johnson et al., 2015) or included strategies focused on organizational process, dose regimens (Harris, Martin, Haneuse, & Ralston, 2009; Neyhart et al., 2010; Schroeder, Fahey, & Ebrahim, 2008). There were a total of six studies related to CKD (Chen et al., 2011; Choi & Lee, 2012; Garcia-Llana, Remor, del Peso, Celadilla, & Selgas, 2013; Jia, Bi, Lindholm, & Wang, 2012; Teng et al., 2013; Welch, Johnson, Zimmerman, Russell, Perkins, & Decker, 2015), 14 studies related to diabetes (Bolen et al., 2014; Duke, Colagiuri, & Colagiuri, 2009; Garcia, Brown, Horner, Zuniga, & Arheart, 2015; Jones et al., 2003; Kim, Hwang, & Yoo (2004); Lepard, Joseph, Agne, & Cherington, 2015; Medical Advisory Secretariat, 2009; Merakou, Knithaki, Karageo, Pal et al., 2015; Partapsingh, Mahara, & Rawlins, 2013; Theodondis & Barbouni, 2015; Naik et al., 2011; Norris, Engelgau, & Narayan, 2001; Rosal et al., 2011; Thoolen, de Ridder, Bensing, Gorter, & Rutten, 2009), seven studies related to hypertension (Bosworth et al., 2009; Friedberg et al., 2015; Hamilton et al., 1993; Johnson et al., 2006; Ogedegbe et al., 2012; Park, Chang, Kim, & Swak, 2013; Ruppap, 2010) and one study included a population of co-morbid hypertension, diabetes and CKD (Williams, Mania, Walker, & Gorelik, 2012).

TABLE 6. *Search Summary Statistics.*

Source	Total Located	Eliminated	Critiqued
PubMed	2435	2426	9
Cochrane	2092	2090	2
EMBASE	524	516	8
PsychInfo	245	245	0
CINAHL	342	339	3
ERIC	127	125	2
Total	5765	5741	24

Study Design/Characteristics

For the purpose of this DNP project only original research, systematic and literature reviews were accepted and critiqued. There were a total of 16 RCTs (Bosworth et al., 2009, Chen et al., 2011; Friedberg et al., 2015; Garcia et al., 2015; Hamilton et al., 1993; Jia et al., 2012; Johnson et al., 2006; Jones et al., 2003; Naik et al., 2011; Ogedegbe et al., 2012; Partapsingh, Mahara, & Rawlins, 2013; Rosal et al., 2011; Ruppap, 2010; Teng et al., 2013; Thoolen et al., 2009; Williams et al., 2012), five quasi-experimental studies (Choi & Lee, 2012; Garcia-Llana et al., 2013; Kim, Hwang, & Yoo, 2004; Merakou et al., 2015; Park et al. 2013) and seven systematic reviews/meta-analyses (Boolen et al., 2014; Duke et al., 2009; Lepard et al., 2015; Medical Advisory Secretariat, 2009; Norris et al., 2001; Pal et al., 2013; Welch et al., 2015). The studies were conducted between the years of 1993 (Hamilton et al., 1993) and 2015 (Friedberg et al., 2015; Garcia et al., 2015; Welch et al., 2015). A variety of communication processes were utilized and compared to either usual care or another type of self-management intervention; one study had no control group (Garcia-Llana et al., 2013). A variety of providers conducted the interventions including registered nurses, nurse practitioners, counselors, health educators and primary care providers. A majority were conducted by a registered nurse (Bosworth et al., 2009;

Chen et al., 2011; Choi & Lee, 2009; Garcia et al., 2015; Park et al., 2013; Ruppert, 2010; Teng et al., 2013; Williams et al., 2012). The identified studies are categorized and synthesized based on chronic condition and will be discussed in further detail below. In studies that utilized instruments or questionnaires, results will be discussed in each section, however specific details of the instruments and scoring are noted in Appendix C. Summary of results including level and quality of evidence is also presented in Appendix C.

CKD

RCTs and Quasi-Experimental Studies

eGFR. Three of the six articles with a CKD population had a primary outcome measure of eGFR calculated by the MDRD equation (Chen et al., 2011; Choi & Lee, 2012; Jia et al., 2012). Two studies compared the intervention to usual care (Choi & Lee, 2012; Chen et al., 2011). Chen et al. (2011) randomly assigned 54 adults with late stage (III-V) CKD to participate in the self-management support (SMS) intervention or usual care for one year (Level I/B). The authors aimed to examine the impact of the SMS on patient outcomes. The average age of the participants were 68.2 years old, approximately 55.6% were males and among all participants, the mean eGFR was 25.38 ml/min. SMS included written educational materials, monthly standardized and face-to-face individualized lectures, weekly telephone consultation, bi-weekly support groups and biannual dietary consultation for one year. The authors emphasized the interactive nature of the intervention. Following the intervention, eGFR was significantly higher in SMS with a mean eGFR 29.11 ± 20.61 ml/min compared to 15.72 ± 10.67 ml/min ($p < 0.05$). Hospitalization events were also significantly lower in the intervention group with only 18.5% compared to 44.47% ($p < 0.05$). Authors determined that the standardized SMS intervention

effectively slowed renal progression and reduced morbidity among late-stage CKD patients (Chen et al., 2011).

Another study (Choi & Lee, 2012), tested a face-to-face small group self-management intervention against usual care among 62 adults with CKD (Level II/B). Authors used a non-equivalent, non-synchronized design. The control group participated in the study first to prevent contamination of the experiment. The purpose of the study was to examine the effects of a self-management education intervention on knowledge, self-care and kidney function. The males in the intervention group accounted for 67.7%, 41.9% were older than 60 years and had a mean eGFR of 38.60 ml/min. In the control group, 70% were male, 50% were older than 60 years and the mean eGFR was 43.93 ml/min. Participants in the intervention group attended one weekly session with a pre-session individualized consultation for three weeks. Topics focused on understanding CKD and motivating participants to self-manage, identify tasks to accomplish in order to engage in positive dietary and exercise behaviors and discuss renal replacement therapies (RRT) to emphasize the importance of adhering to treatment in order to avoid RRT. One week following the last session, a reinforcement education session was conducted. The study did not identify any difference in eGFR between groups. However, there was a significant improvement in self-care and CKD knowledge. Knowledge of CKD scale scores increased from 10.32 to 14.22 at four weeks to 15.41 at eight weeks compared to 11.13 to 11.50 (four weeks) to 11.40 (eight weeks) ($p < 0.001$) for control. Self-care practice scale scores also significantly increased in intervention compared to control (3.55 to 3.88 at eight weeks compared to 3.79 to 3.85 in control $p = 0.001$) implying that self-care practices improved after the intervention. The reinforcement session did not provide any additional improvement in self-care practices (Choi &

Lee, 2012). Authors suggest that a longer follow-up may be needed to fully realize the effects of the intervention on eGFR (Choi & Lee, 2012). The authors concluded that providing structured education with individualized consultation with a provider is more effective than usual care and education in improving knowledge and self-care behaviors. This increases the opportunities for the patient to directly interact with the health-care team by identifying individual barriers and needs in order to successfully manage CKD (Choi & Lee, 2012).

The final study (Jia et al., 2012) assessing eGFR was a retrospective study that grouped 302 adult patients with CKD stage 3-5 into short-term education (S-MIP) or long-term education (L-MIP) based on how many hours of education participants received in an outpatient clinic (Level III/A). The purpose of the study was to assess the effectiveness of multi-dimensional education in slowing the progression of kidney function and whether this was effected by the number of hours of education. The primary outcome was the length of time to show a 25% decline in kidney function based on eGFR. eGFR was calculated using a modified version of MDRD equation for Chinese. The intervention consisted of face-to-face group session multi-dimensional education, skills coaching and motivational activities, i.e. group discussions, storytelling, barrier identification and problem solving (Jia et al., 2012). Two hour skills coaching on lifestyle and self-management behavior was taught once a week by a dietitian in addition to 1.5 hours of CKD-related knowledge taught once a week by a nephrologist or nurse between February 2006 and March 2008. Hours of education had a cut-off value of 12 hours during the study period. The authors identified that the decline in eGFR was significantly faster in S-MIP compared with L-MIP ($p=0.0334$) although no specific values were given. The authors completed a multivariate regression analysis and plotted these values on a graph showing

a faster downwards trend in eGFR in the S-MIP group. L-MIP was also associated with significantly lower SBP (128 mmHg versus 131 mmHg, $p=0.05$) and DBP (72 mmHg versus 77 mmHg, $p=0.03$). There was no statistical difference in other physical factors such as BMI, hemoglobin and serum albumin. Based on the data collected, the authors determined that individuals who received more hours of CKD multi-dimensional education were more likely to progress slower and have better BP control (Jia et al., 2012). A more rigorous research design needs to be tested whether this is applicable to the general population.

Self-care and psychosocial outcomes. Teng et al. (2013) compared a face-to-face stage-matched individualized (based on readiness to change) consultation with a provider to standard education on healthy eating and written materials for one year in four outpatient clinics (Level I/B). There were 160 adult CKD participants with a mean age of 63.9 years, 71% were males and had a mean GFR of 51.7 ml/min. The objective of the study was to test the ability of the stage-matched intervention to modify dietary and exercise behaviors among patients with CKD. Consultations occurred once every three months following the completion of the Transtheoretical Model Staging Inventory. This allowed the provider to identify the individual's readiness to change and adapt interventions accordingly. The intervention promoted positive dietary and exercise behaviors and helped participants to identify barriers, problem solve and set goals. Approximately 60% of participants in intervention moved from non-action stages to action stages compared to only 13% in control group. Additionally, although Renal Protection Knowledge (RPK) scores significantly improved in both groups, only the intervention group had a significant increasing trend of RPK score, approximately 92/100 at baseline to 98/100 after twelve months ($p=0.001$). This indicated that as time went on, patients in the intervention group

continued to build upon knowledge to protect kidney function. The stage-matched intervention was effective in improving RPK and increased the likelihood of participants engaging in self-management behavior.

The single-group quasi-experimental study by Garcia-Llana et al. (2013) tested a behavioral modification intervention on 42 participants with CKD (Level II/B). The authors utilized motivational interviewing techniques (MI) based on the stages of change (SOC) to assess effects on self-care behaviors and psychosocial outcomes. There was no control group. The mean age of the participants was 64 years, 60% were males and 100% had CKD and hypertension. The primary outcome measures were medication adherence, depression and health-related quality of life (HRQL). The intervention was divided into six, monthly 90-minute individual face-to-face sessions and like the other CKD-related studies, included positive reinforcement, barrier identification and problem-solving to enhance self-management. Adherence was determined by a nine-item Survey of Adherence to Treatment, four-item Morisky-Green-Levine test to test medication adherence to oral medications and five-item Stages of Behavior Change related to Oral Medication Compliance Assessment Scale. Depression was assessed by the Beck Depression Inventory and the State-Trait Anxiety Inventory. The 36-item Short Form 36 Health Survey, version 2 was used to evaluate health-related quality of life (Garcia-Llana et al., 2013). Survey of Adherence to Treatment scores increased significantly from 27.12 to 31.4 ($p < 0.001$); the maximum score of 37 indicated a high level of adherence. Additionally, Morisky-Green-Levine test indicated that non-adherence rates decreased from 29% pre-intervention to 16% post-intervention ($p < 0.001$). Furthermore, approximately 60% of participants moved to active stage of change (SOC) from 39% pre-intervention. Depression and anxiety scores also significantly

improved (M= 10.92 to M=8.86, $p=0.05$; M=18.22 to 14.41, $p=0.03$, respectively). In relation to HRQL only domains of general health (M= 37.15 to M=45.97, $p<0.01$) and emotional role (M=71.82 to M=77.57, $p<0.01$) had significant improvements in mean scores (Garcia-Llana et al., 2013). The study suggests that motivational interviewing using the SOC is effective in promoting medication and treatment adherence among patients with CKD (Garcia-Llana et al., 2013). Medication and treatment adherence is an important self-care activity in patients with CKD especially if aimed to control BP or blood sugar. CKD will rapidly decline if co-morbid conditions are not adequately managed (Levey & Coresh, 2012; McClellan, 2005).

Systematic Review

An integrative literature review of a mixture of seven RCTs and quasi-experimental studies related to self-management interventions in stages 1-4 CKD adult patients was conducted by Welch et al. (2015) (Level III/B). The objective of the review was to identify gaps in the current literature and suggest future directions for research. The strategies tested by the various self-management interventions were either theory-based, included motivational interviewing and problem-solving or focused on skill development. All were conducted in person in either an outpatient nephrology clinic, primary care clinic or hospital. Sample sizes ranged from 30-81 participants. The most frequent delivered content was associated with hypertension or self-management while action planning was the most frequent technique used. Three studies provided individual sessions while four studies provided group sessions. The intervention sessions lasted between 30 to 180 minutes per session and had between one to 36 sessions during the intervention period (Welch et al., 2015). Mean age of the participants ranged from 57.5 to 67 years and between 52-69% were men. One study that used action planning and goal setting found

that the annual decline of eGFR was slower in the intervention group (1.2%) compared to control (11.2%). However, of the three studies that had a primary outcome measure of eGFR, results found no significant improvement. Two studies tested medication adherence using education and goal-setting. One study found a significant improvement in medication adherence while one did not. In the study that did not determine any improvement, the study utilized pill counts and thirty of the 75 participants had missing or incomplete data. Additional results can be found in Appendix C. Overall, the authors determined that the current evidence lacked complete educational content and most lacked the inclusion of decision making, resource utilization or self-tailoring. Future studies need to also determine the best time to evaluate outcomes such as eGFR and longer follow-up may be needed to properly assess the efficacy of the intervention. Additionally, the authors recommend a theory to guide studies and intervention development. The authors were unable to form adequate conclusions regarding the effectiveness of the interventions due to insufficient methodological rigor (Welch et al., 2015).

The results of the RCTs/Quasi-experimental studies were split in terms of the effectiveness of the self-management interventions on improving or slowing the progression of CKD. The two studies (Chen et al., 2015; Jia et al., 2012) that identified positive benefits towards eGFR were similar in that they employed multi-dimensional, interactive and individualized techniques (Level I/B; Level III/A). Although one was conducted in a group session, the provider included opportunities for the participants to express his or her individual experiences related to CKD and helped identify barriers and problem-solve in order to improve self-management (Jia et al., 2012). Similarly, the study by Garcia-Llana et al. (2013) utilized tailored motivational interviewing based on the individual's SOC which resulted in significant

improvements in adherence and some psychosocial measures (Level II/B). Compared to usual care or usual education, multi-dimensional interventions that included some form of motivation or individualized education/interaction were significantly more successful in improving eGFR (Chen et al., 2015) or self-care behaviors and knowledge (Choi & Lee, 2012; Teng et al., 2013). Although the authors of the systematic review were unable to identify firm conclusions regarding the effectiveness of the interventions, the authors identified various gaps in the current self-management interventions. Many of the interventions focused on knowledge development and authors felt that there was a lack of decision making, resource utilization and self-tailoring. Of the interventions that were successful in slowing the progression of kidney function, the study employed action planning and individualized goal setting techniques and the other which was successful in improving medication adherence combined verbal education and individualized goal-setting (Welch et al., 2015). Tables 7 and 8 provide summaries of the self-management interventions based on the outcome measure of eGFR or self-care behaviors. The interventions in the tables are organized with the most effective intervention appearing first.

TABLE 7. *Summary of Self-Management Interventions for CKD with eGFR or Physiological Measures (BP Control, BMI, etc.) as an Outcome.*

First Author	Level of Evidence	Individual or Group Session	Length and Frequency of Sessions	Communication Processes	Outcome(s)
Chen	Level I/B	Individual	Monthly individualized CKD lectures x 12 months. Weekly individual telephone consultation Bi-monthly support group No discussion of length of session	Standardized instruction booklet Individualized written materials and didactic lectures Face-to-face Collaborative, positive reinforcement and encouragement	eGFR significantly higher in SMS group 29.11 ml/min vs 15.72 ml/min (p<0.05) post intervention. Baseline eGFR 27.13 ml/min (intervention) and 23.53 ml/min (control). One patient (3.7%) in SMS group vs nine patients (33.3%) in non-SMS had eGFR reduction (worsening) of >50% (P<0.05).
Choi	Level II/B	Both	Weekly sessions for three weeks. Pre-session individual consultation for 20 minutes. Education sessions for 90 minutes.	Power points with verbal education Face-to-face Motivation, encouragement, barrier identification and goal-setting.	No significant difference in physiological factors including eGFR. Longer follow-up to fully realize effects on physiological indicators of kidney function.
Jia	Level III/A	Group	Twice a week—one day 2 hours skills training and one day 1.5 hours of CKD knowledge up to 12 hours	Didactic lectures Face-to-face Story-telling, barrier identification, coaching and problem-solving	eGFR declined significantly faster in patients who received less education (p=0.0334). Longer education associated with significantly lower SBP (128 mmHg versus 131 mmHg, p=0.05) and DBP (72 mmHg versus 77 mmHg, p=0.03). No difference in BMI, Hemoglobin or Albumin

TABLE 8. *Summary of Self-Management Interventions for CKD with Self-Care Behavior as an Outcome.*

First Author	Level of Evidence	Individual or Group Session	Length and Frequency of Sessions	Communication Processes	Outcome(s)
Garcia-Llana	Level II/B	Individual	Monthly sessions lasting 90 minutes each for one year	Motivational interviewing Written materials and didactic lectures Face-to-face Positive reinforcement, barrier identification, problem-solving, stage-matched	Survey of Adherence to Treatment scores increased significantly from 27.12 to 31.4 ($p < 0.001$); the maximum score of 37 indicated a high level of adherence. Non-adherence rates decreased from 29% pre-intervention to 16% post-intervention ($p < 0.001$) Approximately 60% of participants moved to active stage of change (SOC) from 39% pre-intervention indicating more involvement in self-care
Teng	Level I/B	Individual	Once every three months for 1 year No discussion of length of session	Standardized protocol Verbal education Face-to-face Collaborative, stage-matched, problem-solving, goal setting, positive-reinforcement and encouragement	Improvement in self-care behavior. 60% moved from non-action to action stages. Renal Protection Knowledge (RPK) scores significantly improved in both groups, only the intervention group had a significant increasing trend of RPK score; approximately 92/100 at baseline to 98/100 after twelve months ($p = 0.001$).
Choi	Level II/B	Both	Weekly sessions for three weeks. Pre-session individual consultation for 20 minutes. Education sessions for 90 minutes.	Power points with verbal education Face-to-face Motivation, encouragement, barrier identification and goal-setting.	Self-care practice scale scores significantly increased in intervention compared to control (3.55 to 3.88 at 8 weeks compared to 3.79 to 3.85 in control $p = 0.001$).

Diabetes

RCTs and Quasi-Experimental Studies

Hemoglobin A1C or glycemic control. Seven of the eight original research studies included hemoglobin A1C or glycemic control as a primary outcome measure (Garcia et al., 2015; Jones et al., 2003; Kim, Hwang, & Yoo, 2003; Merakou et al., 2015; Naik et al., 2011; Partapsingh, Mahara, & Rawlins, 2013; Rosal et al., 2011). Five studies were in favor of a self-management intervention and found significant improvements in glycemic control (Garcia et al., 2015; Kim, Hwang, & Yoo, 2003; Merakou et al., 2015; Naik et al., 2011; Rosal et al., 2011). Two studies lasted for three months (Kim, Hwang, & Yoo, 2003; Naik et al., 2011), one for three weeks (Merakou et al., 2015) and two studies were conducted over a course of one year (Garcia et al., 2015; Rosal et al., 2011). Rosal et al. (2011) tested a theory-based, literacy and culturally tailored self-management intervention versus usual care (Level I/A). The intervention group received 12 weekly face-to-face interactive group sessions with a one-hour pre-session personal consultation with goal setting and problem solving. After 12 weeks, participants received eight monthly follow-up sessions. The intervention group had significant improvements and better control of A1C compared to the control group following the intervention but results were not sustained at 12 months. The number of participants with a HgbA1C <7% at 4 months was 29.1% (intervention) versus 12.4% (control), $p=0.013$ and at 12 months 23% (intervention) versus 16.2% (control), $p=0.233$ (Rosal et al., 2011).

Naik et al. (2011) compared two interventions to test the effects on A1C levels in the primary care setting (Level I/B). The control group received two, two-hour standard group education sessions spread between three months followed by a 20-30-minute office visit with the

primary care provider. The intervention group received The Empowering Patients in Care (EPIC) intervention which was divided into four, 1-hour interactive group sessions that focused on goal setting, action planning, and goal attainment (evaluation). Following each group session participants received 10-minutes of individualized consultation to help empower patients to self-manage their disease. Results showed a greater improvement in HgbA1C with a mean (SD) between group difference of 0.67% (1.3%) $p=0.03$ three months post-intervention which persisted at 1-year follow-up with 0.59% (1.4%), $p=0.05$. However, there was no growth in improvement after 1 year (Naik et al., 2011). The pilot study by Garcia et al. (2015) found similar results in that there was a statistically and clinically significant improvement in A1C immediately following the intervention compared to the control group (8.6% to 7.8%, $p<0.001$ versus 8.6% to 8.3%, $p= 0.609$), however improvement was not sustained after 6 months (Level I/B). The study tested eight, weekly in home one-on-one education and behavior modification sessions with a registered nurse that tailored interventions based on symptoms, focused on glucose self-testing and helped participants identify barriers and problem solve. After eight weeks, the participants received eight biweekly telephone support calls to help reinforce self-care behaviors (Garcia et al., 2015). All three studies concluded that a self-management intervention was more successful than usual care and standard education in improving A1C although results were not sustained in long-term follow-up. Further research is needed in order to identify strategies that may help sustain results (Garcia et al., 2015; Naik et al., 2011; Rosal et al., 2011). Additional results and patient demographics of these studies can be found in Appendix C.

The remaining two studies that identified significant improvements in A1C compared to standard education used pre-planned counseling strategies (Kim, Hwang, & Yoo, 2003) and

conversation maps (CM) which allowed providers to take a standardized approach (Merakou et al., 2015). One tested a 2-hour once a week structured face-to-face group patient education using (CM) which included group discussions, questions and answers and scenarios. CM were interactive tools with pictures and topics that stimulated discussion and participation (Merakou et al., 2015, Level II/A). HgbA1C statistically improved in both groups but improved more in intervention compared to control (-0.6% difference in A1C (95% CI: -0.8, -0.3, $p < 0.001$) vs. -0.5% difference in A1C (95% CI: -0.5, -0.3 $p = 0.003$). Kim, Hwang, & Yoo (2003) conducted an individual face-to-face stage-matched self-management intervention (Level II/B). Participants received one individualized 60-90 minute behavior training and stage-matched counseling with a registered nurse and twice a week 10-30 minute telephone counseling with positive reinforcement and problem-solving for three months. The stage-matched counseling was pre-planned and included standardized counseling strategies to adopt and maintain exercise behaviors based on the individual's readiness to change (Kim, Hwang, & Yoo, 2003). The results indicated a significant reduction in fasting blood sugar (FBS) 156.32 to 139.14 (intervention) versus 153.74 to 164.35 (control), $p = 0.03$ and A1C 7.84% to 6.96% (intervention) versus 7.78% to 8.19% (control), $p = 0.02$. Supplementary measurements, results and patient demographics for these studies can be found in Appendix C. Both of these studies suggest that using a standardized approach to self-management may help improve patient outcomes more specifically related to A1C among patients with Type 2 diabetes (Kim, Hwang, & Yoo, 2003, Merakou et al., 2015).

The other studies which were both stage-matched interventions did not find any significant difference between the intervention or control. In one study (Partapsingh, Mahara, & Rawlins, 2013), 119 adult Type 2 diabetics in Trinidad were random allocated to a stage-specific

personalized consultation in an outpatient clinic that occurred once every 16 weeks for 48 weeks or usual care (Level I/B). The providers used standardized checklists based on the individual's stage of change to ensure all pertinent topics and interventions were addressed. The average age of the participants ranged from 40-59 years old, 64% in intervention were men compared to 66% in control. Between both groups, 34% have been a diabetic for at least five years. The objective of the study was to improve glycemic control by using Stages of Change model to guide patient-provider consultations. The results showed an unexpected worsening of glycemic control. However, the authors did note that the intervention resulted in a significantly less increase in HgbA1C among the intervention group (0.57% less (95%CI 0.07 - 1.07, p 0.025)) (Partapsingh, Mahara, & Rawlins, 2013). The authors believed that economic hardships in Trinidad limited the intervention group in that they did not have the financial capability to fully carryout the intervention (Partapsingh, Mahara, & Rawlins, 2013).

The second study (Jones et al., 2003) randomly assigned 1029 newly diagnosed Type 1 and Type 2 adult diabetic participants to the pathway to change (PTC) intervention or usual care and were followed for 12 months (Level I/B). The authors sought to identify whether PTC would result in greater readiness to change, greater improvement in self-care and improved diabetes control. There were four groups: 1) PTC alone, 2) PTC with free test strips, 3) Treatment as Usual alone (TAU) and 4) TAU with free test strips. Mean age of the participants were 54.58, 55.12, 54.85 and 54.60 years respectively. The mean years since diagnosis of diabetes was between 10.09 (PTC alone) and 11.15 (TAU alone). The participants received monthly stage-matched personalized assessment reports, self-help, or individual phone counseling. Interventions provided were specifically related to participant needs and included either self-

monitoring blood glucose (SMBG), healthy eating or smoking cessation or combination. HgbA1C was retrieved via venous blood sampling and Stage of Change was determined by self-reported specific action criterion that was constructed based on the TTM. Results did not identify a significant difference in HgbA1C between groups. However, in participants that moved to an action stage of SMBG and healthy eating, HgbA1C was significantly decreased; 7.78% compared to 8.3% in participants who remained in pre-action ($p < 0.003$). PTC alone and PTC with free strips resulted in an increase percentage of participants moving to action and maintenance stages. This means that a higher percentage of participants were engaging in self-management behavior. The study determined that PTC was more successful than TAU in moving participants to action stages of diabetes self-management which in the long-term may have a positive impact on individual health (Jones et al., 2003).

Self-care. The remaining original research (Thoolen et al., 2009) tested a brief self-management intervention based on proactive coping compared to usual care in 180 newly diagnosed Type 2 diabetics (Level I/A). The purpose of the study was to achieve sustained improvement in self-care behaviors. In the intervention group, the mean age of the participants was 62.0 years, 64% were men and had a mean duration of diabetes for 18.4 months. In the control group the mean age of participants were 61.9 years, 55% were men and the mean duration of diabetes was 17.0 months. The primary outcome measure was self-care related to diet, medication and exercise. Additional outcomes were related to proactive coping. The intervention included a mixture of two face-to-face individual sessions and four, two-hour face-to-face group sessions in which participants were mentally stimulated and coached to set goals, evaluate goals and plan for the future over 12 weeks. Multiple instruments and questionnaires

were utilized to assess self-care measures and proactive coping and are discussed in detail in Appendix C. Participants in the intervention group improved in all self-care measures except for medications at 12 weeks and nine months (np^2 (effect size)- 0.02-0.10). More specifically, means scores of the Diabetes Self-Care Activities (DSCA) measure significantly increased from 3.5 to 4.1 ($p < 0.001$) after 9 months compared to no change in scores among the control group (Thoolen et al., 2009). This indicated that participants in the intervention group significantly improved in engaging in self-care behaviors. Medication adherence likely did not improve due to the high level of adherence prior to the start of the intervention; participants had little room for improvement. Proactive competence scores also significantly improved post-intervention from 2.9 to 3.2 ($p < 0.01$) after nine months compared to 2.9 to 3.0. Proactive coping is a significant predictor of long-term self-management ($p < 0.01$) (Thoolen et al., 2009). The authors determined that developing achievable individualized goals and evaluating success whether it be in one-on-one or group sessions is key to sustained behavioral change (Thoolen et al., 2009).

Systematic Reviews/Meta-Analyses

Hemoglobin A1C or glycemic control. Six systematic reviews/meta-analyses were extracted and reviewed. In some articles, a meta-analysis was not feasible due to variability in outcomes measures (Lepard et al., 2015; Norris, Engelgau, & Narayan, 2001). All reviews included studies with at least one primary outcome measure focused on glycemic control (Bolen et al., 2014; Duke, Colagiuri, & Colagiuri, 2009; Lepard et al., 2015; Medical Advisory Secretariat, 2009; Norris, Engelgau, & Narayan, 2001; Pal et al., 2013). Pal et al. (2013), Level I/A, reviewed 16 RCTs of computer-based self-management interventions, Medical Secretariat (2009), Level I/A, reviewed 12 RCTs of multi-faceted behavioral interventions with a majority

focusing on problem solving, goal setting, and empowerment, Norris, Engelgau and Narayan (2001), Level I/A, reviewed 84 RCTs of self-management training including multi-component interventions with education focused on information, life-style behaviors, mechanical or coping skills, Duke, Colagiuri, & Colagiuri (2009), Level I/A, conducted a meta-analysis of nine RCTs that compared individual education vs usual care or individual education vs group education, Bolen et al. (2014), Level I/A also conducted a meta-analysis of 138 RCTs focused on enhancing patient activation (i.e., problem solving, audit & feedback, skill building, etc.) and the final systematic review by Lepard et al. (2015), Level III/A, reviewed a mixture of RCTs and quasi-experimental studies regarding diabetic self-management (DSME) strategies that included either collaborative goal setting, individual or group education, telehealth communication or culturally tailored information. There was a wide range of the duration of the interventions; one review identified a study with one week (Norris, Engelgau, & Narayan, 2001) and one as long as eight years (Medical Secretariat, 2009). All of the participants were adults with Type 2 diabetes and were recruited from various settings with a majority in primary and outpatient clinics. Almost all tested an intervention that was multi-dimensional meaning that it included multiple strategies other than didactic education in order to improve self-care and/or patient outcomes.

All six reviews found a significant improvement in glycemic control especially in interventions that were empowering, individualized and included collaborative discussions (Lepard et al., 2015; Medical Advisory Secretariat, 2009; Norris, Engelgau, & Narayan, 2001; Pal et al., 2013). In one study, significant improvement was only found in participants who received individual education and had a higher baseline A1C (Duke, Colagiuri, & Colagiuri, 2009). Additionally, in some, the improvement was significant but minimal (Medical Advisory

Secretariat, 2009; Pal et al., 2013). A meta-analysis of RCTs of multi-faceted behavioral interventions including empowerment, problem solving and goal-setting found a reduction of HgbA1C levels by 0.44% 95% CI -0.60, -0.29 compared to usual care (Medical Advisory Secretariat, 2009). In RCTs that enhanced patient activation through various strategies of feedback, auditing and problem solving found that no specific strategy significantly outperformed the others but did find that all improved A1C (Bolen et al., 2014). Larger effects were found in diabetics with higher baseline A1C greater than 7-9% (Bolen et al., 2014; Duke, Colagiuri, & Colagiuri, 2009; Medical Advisor Secretariat, 2009; Pal et al., 2013). Diabetics with A1C >7% had a weighted measure difference (WMD) of -0.3% 95% CI -0.5 to -0.1, $p=0.001$ between individual education and usual care (Duke, Colagiuri, & Colagiuri, 2009). Similarly, RCTs of behavioral interventions had a larger decrease in A1C among poorly controlled diabetics -0.79% 95% CI -1.23 -0.34 versus -0.40% 95% CI -0.55 -0.24 usual care (Medical Advisory Secretariat, 2009). Additional results and details such as patient demographics regarding the systematic reviews/meta-analyses can be viewed in Appendix C.

Self-care. Of the six systematic reviews/meta-analyses only two included self-care/self-efficacy as a primary or secondary outcome measure (Norris, Engelgau, & Narayan, 2001; Pal et al., 2013, Level I/A). Norris, Engelgau, & Narayan (2001) did not conduct a meta-analysis. In this systematic review, 84 articles were analyzed and classified into one of four categories based on educational focus: knowledge or information, lifestyle behaviors, skill development and coping skills (empowerment techniques, relaxation techniques or self-efficacy) (Norris, Engelgau, & Narayan, 2001). Of the studies reviewed, most that examined dietary habits found positive self-reported changes in dietary or carbohydrate intake. Only two studies failed to show

improvement in diet. Furthermore, in eight studies that tested a self-management intervention to improve engagement in physical activity, three studies showed improved physical activity while five showed no change. Overall, the systematic review identified mostly positive effects towards self-care and noted that collaborative interventions were more successful than didactic interventions (Norris, Engelgau, & Narayan, 2001). The systematic review and meta-analysis of 16 RCTs of computer-based self-management focused on applications that respond to participant input and provide tailored content (i.e., reinforcement, motivation, goal-setting, problem solving, etc.) (Pal et al., 2013, Level I/A). Computer-based interventions were either conducted at home, on an outpatient clinic kiosk or on mobile applications. Authors found that the majority of the studies reviewed reported statistically significant improvements in physical activity and dietary adherence among intervention groups. When combined in a meta-analysis there were significant improvements in dietary change scores using computer-based interventions with a standardized mean difference (SMD) of -0.29 (95% CI: -0.43 to -0.15; 89 participants, three trials) (Pal et al., 2013). Despite these results, the authors were unable to make definitive conclusions and found that computer-based interventions are still poorly understood and need further research (Pal et al., 2013). As previously mentioned, further detail can be found in Appendix C.

The RCTs and Quasi-experimental studies mostly found more favorable outcomes after self-management interventions compared to usual care or standard education. The most common theme among the studies that found significant improvements in glycemic control or self-care behaviors were interactive and collaborative (Lepard et al., 2015, Level III/A; Medical Advisory Secretariat, 2009, Level I/A; Norris, Engelgau, & Narayan, 2001, Level I/A; Pal et al., 2013, Level I/A). In two studies, the authors used a standardized approach (Kim, Hwang, & Yoo, 2003,

Merakou et al., 2015). This suggests that self-management interventions may result in better outcomes among patients with Type 2 DM compared to usual care or standard education and therefore have the potential to decrease risks related to CKD. The systematic reviews found similar results and all studies that tested an intervention to improve glycemic control resulted in significant improvements. There was a mixture of individual and group sessions however the most common themes of the interventions were empowering, included an individualized component and involved collaborative discussions. Both reviews including self-care or self-efficacy as an outcome measure also found significant improvements. In one review collaborative interventions were more successful than didactic interventions (Norris, Engelgau, & Narayan, 2001, Level I/A). In the other, the authors could not identify a more successful computer-based intervention and suggested that these interventions were poorly understood (Pal et al., 2013, Level I/A). Table 9 and 10 includes a summary of the interventions pertaining to the outcome measure of glycemic control or self-care behaviors. The interventions are listed from highest impact to lowest.

TABLE 9. *Summary of Self-Management Interventions for Diabetes with Hemoglobin A1C or Glycemic Control as an Outcome.*

First Author	Level of Evidence	Individual or Group	Length and Frequency of Sessions	Communication Processes	Outcome(s)
Naik	Level I/B	Both	4 group sessions over 3 months- 1-hour group interaction and 10- minute individualized consultation follow group session.	Standardized participant manual Written materials and interactive discussions Face-to-face Interactive, goal setting, action planning and evaluation	Significantly greater improvement in HgbA1C mean (SD) between group difference of 0.67% (1.3%) (p=0.03) three months post intervention. Improvement persisted at 1-year follow-up (0.59% (1.4%), p=0.05). No growth in improvement after 1 year.

TABLE 9. – *Continued.*

First Author	Level of Evidence	Individual or Group	Length and Frequency of Sessions	Communication Processes	Outcome(s)
Kim	Level II/B	Individual	Individual face-to-face stage-matched counseling, behavior training (one 60-90-minute session) plus twice a week 10-30-minute telephone counseling with positive reinforcement and problem-solving for 3 months.	Standardized pre-planned counseling interventions Face-to-face and telephone Positive reinforcement, problem-solving, stage-matched	Significant reductions in FBS 156.32 to 139.14 (intervention) versus 153.74 to 164.35, $p=0.03$ (control) Significant improvement in Hemoglobin A1C 7.84% to 6.96% versus 7.78% to 8.19%, $p=0.02$.
Rosal	Level I/A	Both	12 weekly face-to-face sessions with first hour of personal consultation and then group sessions. After 12 weeks, 8 monthly follow-up sessions	Standardized detailed protocol Face-to-face Culturally-tailored Interactive, goal-setting and problem solving	HgbA1C <7% (well-controlled diabetes) at 4 months 29.1% (intervention) vs. 12.4% (control, $p=0.013$). Improvement not sustained at 12 months 23% vs. 16.2% ($p=0.233$)
Garcia	Level I/B	Individual	Six, monthly 90-min individual face-to-face session	Face-to-face Individualized verbal education Motivational interviewing Interactive, skills training, problem-solving, encouragement, tailored to symptoms.	Statistically and clinically significant improvement in A1C immediately following the intervention compared to the control group (HgbA1C 8.6% to 7.8%, $p<0.001$ versus HgbA1C 8.6% to 8.3%, $p=0.609$), Improvement was not sustained after 6 months
Merakou	Level II/A	Group	2-hour group session once a week for three weeks.	Face-to-face, verbal. Structured education using conversation maps. Role-playing, interactive, problem-solving	HgbA1C statistically improved in both groups but improved more in intervention compared to control (-0.6% (95% CI: -0.8, -0.3, $p<0.001$) vs. -0.5% (95% CI: -0.5, -0.3 $p=0.003$)

TABLE 9. – *Continued.*

First Author	Level of Evidence	Individual or Group	Length and Frequency of Sessions	Communication Processes	Outcome(s)
Partapsingh	Level I/B	Individual	<p>Consultation session was once every 16 weeks for 48 weeks.</p> <p>No discussion of length of sessions.</p>	<p>Standardized counseling checklist</p> <p>Face-to-face</p> <p>Stage-matched</p>	<p>No improvement in glycemic control ($p=0.025$); worsened for both groups but worsened less in intervention</p> <p>SD in glycemic control. HgbA1C mean increase 0.52% (SE 0.17) in intervention compared to 1.09% (SE 0.18) in control group. Economic hardships likely contributing to worsening of glycemic control</p>
Jones	Level I/B	Individual	<p>Monthly contact with personalized reports or telephone counseling x 12 months</p> <p>No discussion of length of telephone counseling</p>	<p>Telephone</p> <p>Stage-matched personalized written report</p> <p>Encouragement and reinforcement</p>	<p>No SD in HgbA1C. Significant reduction in HgbA1C only in participants who reached action or maintenance stages.</p> <p>End HgbA1C 7.78% in participants who received education on self monitoring of blood glucose (SMBG) and reached action/maintenance versus 8.3% who remained in pre-action ($p<0.003$)</p> <p>End HgbA1C 7.83% who received healthy eating education and reached action/maintenance versus 8.38% who remained in pre-action ($p<0.001$)</p>

TABLE 10. *Summary of Self-Management Interventions for Diabetes with Self-Care Behavior as an Outcome.*

First Author	Level of Evidence	Individual or Group Session	Length and Frequency of Sessions	Communication Processes	Outcome(s)
Thoolen	Level I/A	Both	Two individual sessions and 4, 2-hour group sessions	Face-to-face Interactive, proactive coping, individualized goal-setting, problem-solving, encouragement, coaching.	Intervention group significantly better on all self-care measures except for medications at 12 weeks and 9 months (np^2 - 0.02-0.10). Medication adherence was already high pre-intervention. Significant and moderate improvements in proactive competence (2.9 to 3.1 (12 weeks) to 3.2 (9 months), $p < 0.01$ vs 2.9 to 3.0 to 3.0 in control).
Jones	Level I/B	Individual	Monthly contact with personalized reports or telephone counseling x 12 months No discussion of length of telephone counseling	Telephone Stage-matched personalized written report Encouragement and reinforcement	Increase % of participants moving to action and maintenance stages= more participants engaging in self-care. Intervention group (healthy eating focus) more moved to action/maintenance vs control group ($p < 0.001$). 11.4% at maintenance vs 0% control ($X^2 = 26.52$, $p < 0.001$). More quit smoking 17.8% action, 5.5% maintenance (intervention) vs 11.5% action 0% maintenance (control)

Hypertension

RCTs and Quasi-Experimental Studies

BP control. There were seven studies relating to adult participants with high BP. Five of the seven studies tested BP control as a primary outcome measure (Bosworth et al., 2009; Friedberg et al., 2015; Hamilton et al., 1993; Park et al., 2013; Ruppert, 2010). All of the studies included an individually tailored intervention. Two studies tested individualized telephone counseling (Bosworth et al., 2009; Friedberg et al., 2015). Bosworth et al., (2009) tested the

effects of two self-management interventions for improving BP control among 636 adult hypertensive participants (Level I/A). Mean age of the participants was 61 years, 49% were African American, 66% female with a baseline BP 125/71. BP control was based on JNC 7 guidelines. There were four groups: 1) Usual care, 2) Tailored bi-monthly individual behavioral phone intervention only, 3) Home BP monitoring with logs mailed every two months and 4) Combination (behavioral phone intervention) + home BP monitoring). The intervention lasted for two years. Improvements in proportion of BP control relative to usual care was higher in combined group with 11.0% (95% CI: 1.9% 19.89%, $p=0.012$) versus 4.3% (95% CI: -4.5%, 12.9%, $p=0.34$) in behavioral phone intervention only and 7.6% (95% CI: -1.9%, 17%, $p=0.096$) in home BP monitoring only. Additionally, 24 months mean SBP and DBP was significantly lower only in combined group (-3.9 mmHg, 95% CI: -6.9%, -0.9, $p=0.010$; -2.2 mmHg, 95% CI: -3.82%, -0.6%, $p=0.009$ respectively) (Bosworth et al., 2009). The study by Friedberg et al. (2015) also tested two behavioral interventions against usual care for six months (Level I/A). There were three groups: 1) Usual care (UC), 2) Stage-mediated intervention (SMI) and 3) Non-tailored interactive health education (HEI). The SMI was a tailored interactive 20-minute individual monthly phone counseling for exercise, diet and medications based on SOC while the HEI provided a standard non-tailored 15-minute individual monthly phone counseling for exercise, diet and medications. There were 533 participants with a mean age range of 65.4 to 66.4 years, 97.7% to 99.4% men, and 40.6% to 44.6% had controlled BP. SMI and HEI significantly lowered SBP in 6 months compared to UC 131.2 mmHg vs 134.7 mmHg, $p=0.009$ and 131.8 vs 134.7 $p=0.047$ respectively. Furthermore, 19.7% improved BP among those with controlled BP in SMI group ($p < 0.0001$) compared to 11.9% ($p=0.012$) for HEI and 1.3%

($p=0.76$) for UC. The results of the two tailored telephone-based studies suggest that this avenue of communication is more effective than usual care in improving BP control. However, it is important to note that the other interventions such as home BP monitoring and non-tailored education did have significant improvements in BP although were more favorable in the tailored and interactive interventions (Bosworth et al., 2009; Friedberg et al., 2015).

A behavioral feedback intervention to improve medication adherence and BP control among 15 adults with uncontrolled hypertension was tested against usual care (Ruppar, 2010, Level I/B). Age of the participants ranged from 60-87 years and 73% were female. The intervention utilized face-to-face individualized feedback and habit modification in addition to written educational materials. There were four home visits with a registered nurse over the course of eight weeks. BP control was based on the American Heart Association guidelines and medication adherence was monitored electronically. As a pilot, this study was not powered for statistical significance. However, the results showed an improvement in SBP compared to usual care. At 12 weeks, SBP lowered to 130 mmHg compared to an increase to 152 mmHg in control group. At 12 months, eight of the ten participants in the intervention group had controlled SBP and none in usual care. Percentage of improvement in medication adherence also was higher in intervention group compared to control (15.4% versus 5.6%). The authors concluded that the behavioral feedback intervention has promising benefits towards improving BP control in patients with poorly controlled hypertension (Ruppar, 2010).

Hamilton et al. (1993) compared the effects of Standard Treatment (ST) and Special Intervention (SI) on enhancing medication adherence in order to improve blood pressure control. The study tested the intervention among 34 adults with hypertension (Level I/C). The mean age

ranged between 51.7 to 56.6 years, mean duration of hypertension was 11-12.7 years and mean baseline BP was 157.95/95 mmHg in SI and 144/88.7 mmHg in ST. SI consisted of one, 30-40 minute face-to-face tailored individual counseling with nurse practitioner based on the participant's response to a standardized questionnaire. The counseling included reinforcement of medical regimen, individualized negotiated plan of care, written and 12-minute video education, and problem-solving. The session occurred before a regular follow-up visit with the primary care provider. After one month, the participant received a follow-up phone call to evaluate negotiated plan. Difference in scores of mean SBP was significantly greater for SI group following the intervention with a -0.43 difference vs -0.19, $p=0.02$ (control). There was no significant difference in self-reported adherence however mean Medication Adherences scores were higher in intervention group with 0.38 versus 0.25. These results indicate that SI has the potential to improve medication adherence among patients with hypertension and subsequently lead to improved BP control (Hamilton et al., 1993).

Another study that aimed to improve BP control tested the effects of a tailored self-management intervention among 47 older adults with hypertension compared to usual care (Park et al., 2013, Level II/A). Mean age was 77.4 years, 34% were female with a mean duration of hypertension for 12.5 years. The tailored intervention consisted of bi-weekly sessions; 60-minute face-to-face group health education sessions (group discussions and personal experiences) on Mondays and tailored 30-minute one-on-one individualized counseling that focused on barrier identification, problem solving and strategic planning on Wednesdays. The individualized counseling was based on motivational interviewing strategies. Patient-tailored self-management significantly reduced SBP from 127.6 mmHg to 120 mmHg at eight weeks, $p=0.069$ versus

130.9 mmHg to 132.8 mmHg, $p=0.120$ in control. Following the intervention, participants also had significantly higher improvements in Scale of Self-Care Behaviors of Hypertension scores with an increase by 13.7 points compared to a decrease of 3.4 points in usual care. Findings suggest that a tailored, stage-matched motivational intervention is successful in statistically and clinically improving BP control (Park et al., 2013).

Self-care. Medication adherence was a primary outcome measure in two of the seven studies (Johnson et al., 2006; Ogedegbe et al., 2012). In a three group comparison of 256 hypertensive African Americans grouped by usual care, culturally-tailored patient education workbook (PE) or culturally-tailored patient education workbook with positive affect and self-affirmation discussions with bi-monthly individual telephone interviewing (PA), medication adherence was significantly higher in the PA group than PE group (42% versus 36%, $p=0.049$) (Ogedegbe et al., 2012, Level I/A). Mean age of the participants was 58 years, 77% (control) and 82% (intervention) were women, the mean duration of hypertension was 11 years (control) and 12 (intervention) years and average Medication Adherence scores was 1.2 (control) and 1.0 (intervention). Positive affect telephone counseling induced positive feelings related to medication adherence and motivated the participants to actively engage in self-care behavior. However, despite improvements in medication adherence, there was no significant difference in BP reduction (SBP less 2.14 mmHg in PA and less 2.18 mmHg in PE) between groups (Ogedegbe et al., 2012). Johnson et al. (2006), Level II/B, conducted a study to assess the effects of usual care versus a Pro-Change Program for High Blood Pressure Medication in improving adherence among 1227 adult participants for one year. The mean age of the participants was 55.7 years and no other specific patient characteristics were discussed. The Pro-Change Program for

High Blood Pressure Medication provided stage-matched, individualized written manual with computer generated feedback reports at three and six months. Participants in intervention group had a significantly lower non-adherence rate at 12 months ($p<0.01$) and 18 months ($p<0.001$) in comparison to usual care (Johnson et al., 2006). Additionally, more participants moved to action or maintenance stage at 12 months (73.1% versus 57.6%, $p<0.001$) and 18 months (69.1% versus 59.2%, $p<0.01$) indicating improved self-care behaviors. Compared to usual care, studies suggest that individual tailored written materials in addition to individual feedback and motivation can be successful in improving medication adherence. Although one study did not find a significant difference in BP control, there were minor improvements in BP indicating some positive benefits from the intervention (Ogedegbe et al., 2012).

A review of RCTs of self-management interventions to improve medication adherence and/or blood pressure control was more favorable towards the self-management interventions than usual care. All of the studies found significant improvements in the primary outcome measures (Bosworth et al., 2009; Friedberg et al., 2015; Hamilton et al., 1993; Johnson et al., 2006; Ogedegbe et al., 2012; Park et al., 2013; Ruppert, 2010). Common themes of the interventions were tailored, interactive and most were conducted at an individual level whether it be face-to-face or through telephone. Tables 11 and 12 provide a summary of interventions related to BP control and self-care behaviors. Each table lists the most effective interventions first.

TABLE 11. *Summary of Self-Management Interventions for Hypertension with BP or BP Control as an Outcome.*

First Author	Level of Evidence	Individual or Group	Length and Frequency of Sessions	Communication Processes	Outcome(s)
Friedberg	Level I/A	Individual	<p>Stage-mediated intervention (SMI)- Intervention 1: 20-minute monthly phone counseling</p> <p>Non-tailored interactive health education (HEI) - intervention 2: 15-minute monthly phone counseling for 6 months</p>	<p>SMI- Standardized computer-based intervention manual, interactive, stage-matched, barrier identification, problem-solving, decisional balance and empowerment</p> <p>HEI- interactive, encouragement, verbal education</p>	<p>SMI significantly lowered SBP in 6 months than usual care (131.2 vs 134.7 p=0.009). HEI lowered mean SBP than UC (131.8 vs 134.7 p=0.047).</p> <p>19.7% improved BP among those with controlled BP in SMI group (p <0.0001). 11.9% (p=0.012) and 1.3% (p=0.76) in HEI and UC respectively.</p>
Bosworth	Level I/A	Individual	<p>Intervention 1- Tailored bi-monthly individual behavioral phone intervention only</p> <p>Intervention 2- Home BP monitoring three times a week on three separate days at the same time of day. Mailed logs every 2 months.</p> <p>Intervention 3- Combination (behavioral phone intervention, bi-monthly) + home BP monitoring) Lasted 2 years.</p>	<p>Face-to-face</p> <p>Intervention 1- Individually tailored, interactive, verbal education based on pre-planned modules</p> <p>Intervention 3- Individually tailored, interactive, skills training, verbal education based on pre-planned modules</p>	<p>Intervention 3- significant improvement in BP control compared to usual care; 11.0% improvement BP control (95% CI: 1.9% 19.89%, p=0.012).</p> <p>Intervention 1- 4.3% improvement BP control (95% CI: -4.5%, 12.9%, p=0.34) vs Intervention 2- 7.6% improvement BP control (95% CI: -1.9%, 17%, p=0.096).</p> <p>24 months mean SBP and DBP significantly lower only in intervention 3 group. -3.9 mmHg, 95% CI: -6.9%, -0.9%, p=0.010 (SBP) and -2.2 mmHg, 95% CI: -3.82%, -0.6%, p=0.009 (DBP)</p>
Park	Level II/A	Both	Once a week for 8 weeks- 60-minute face-to-face group health education sessions and 30-minute individualized counseling	<p>Face-to-face</p> <p>Interactive, barrier identification, strategic planning, problem-solving, stage-matched, motivational interviewing</p>	<p>Patient-tailored self-management significantly reduced SBP 127.6 mmHg to 120 mmHg at 8 weeks, p=0.069 versus 130.9 mmHg to 132.8 mmHg, p=0.120 (Control)</p>

TABLE 11. – *Continued.*

First Author	Level of Evidence	Individual or Group	Length and Frequency of Sessions	Communication Processes	Outcome(s)
Ruppar	Level I/B	Individual	Four home visits over eight weeks. No discussion of length of sessions.	Face-to-face Written and verbal education Standardized, tailored, interactive, feedback.	SBP lowered to 130 mmHg at 12 weeks for intervention. Control group increased SBP to 152 mmHg. At 12 months, 8 of 10 participants in intervention group had controlled SBP, none in control group (P=0.007, Fisher exact test).
Hamilton	Level I/C	Individual	One 30-40-minute session, 12-minute educational video, individualized negotiated plan of care.	Face-to-face and telephone Tailored based on standardized questionnaire Written, video and verbal education Collaborative, problem-solving, goal-setting.	Difference in scores of mean SBP significantly greater for SI group, -.43 difference (intervention) vs -.19, p=0.02).

TABLE 12. *Summary of Self-Management Interventions for Hypertension with Self-Care as an Outcome.*

First Author	Level of Evidence	Individual or Group	Length and Frequency of Sessions	Communication Processes	Outcome(s)
Ogedegbe	Level I/A	Individual	<p>Patient Education (PE) Control- Culturally tailored educational workbook</p> <p>Positive affect (PA) Intervention- Culturally tailored educational workbook with positive affect induction and self-affirmation. Individual telephone interviewing bi-monthly x 12 months. No discussion of length of telephone interviews</p>	<p>PE- written education materials, culturally tailored</p> <p>PA- written education materials, telephone, culturally tailored, positive affect induction, self-affirmation</p>	Medication adherence significantly higher in PA than PE group (42% vs 36% respectively, p=0.049)
Park	Level II/A	Both	Once a week for 8 weeks- 60-minute face-to-face group health education sessions and 30-minute individualized counseling	<p>Face-to-face</p> <p>Interactive, barrier identification, strategic planning, problem-solving, stage-matched, motivational interviewing</p>	<p>Self-care behavior significantly increased by +13.7 points, p=0.000.</p> <p>Control group significant worsening of self-care by -3.4 points p=0.001</p>
Johnson	Level II/B	Individual	Written manual with computer generated feedback report at 3 and 6 months.	<p>Written materials and feedback report</p> <p>Stage-matched, feedback, problem-solving, barrier identification, decisional balance</p>	<p>Significantly more in action or maintenance stage at 12 months (73.1% versus 57.6%, p<0.001) and 18 months (69.1% versus 59.2%, p<0.01). Significantly lower nonadherence rate at 12 months (p<0.01) and 18 months (p<0.001).</p>

Co-Morbid CKD, HTN, and Diabetes

RCT

Only one study combined a group of co-morbid CKD, HTN and Diabetic patients in order to test the feasibility and effects of a multifactorial intervention on BP control and medication adherence (Williams et al., 2012, Level I/B). There were 75 participants randomly

allocated to either usual care or the intervention group with face-to-face individual medication review, DVD education and telephone reinforcement conducted by a registered nurse every two weeks for three months using motivational interviewing techniques; the registered nurse utilized a standardized motivational interviewing topic checklist to ensure all pertinent topics were discussed and addressed. The primary outcome measure was attrition rates to test feasibility. At the end of the study, 70 participants remained; three participants died, one withdrew and the other refused to have his BP checked on the final data collection. The study also sought to determine the effectiveness of the intervention on BP control and medication adherence. Medication adherence was determined by pill counts. The number of pills taken was divided by the number of pills that should have been taken. There was no difference in medication adherence between groups using pill counts. The authors discussed that a more structured way to assess medication adherence is needed in order to ensure accuracy of results (Williams et al., 2012). In addition to this, there was no statistical difference in BP control. However, between both groups, only the intervention group had clinically significant improvements in systolic BP (-6.9 mmHg 95% CI versus -3.0 mmHg 95% CI) (Williams et al., 2012). An improvement of 5 mmHg in BP control is associated with improved morbidity and mortality (Williams et al., 2012). The authors concluded that the multifactorial intervention can be easily implemented and participants enjoyed the interactive nature of the sessions. Future studies may need to test a larger sample size and longer follow-up to fully assess the effects on BP control and medication adherence (Williams et al., 2012).

Communication Tool

CKD is a complex chronic illness that requires significant lifestyle and behavioral changes in order to reduce individual risk and slow the progression of the disease (Devraj & Wallace, 2013). Knowledge alone is not sufficient to promote self-care behaviors among patients with CKD (Teng et al., 2013). Additionally, the way a provider communicates to the patient can positively or negatively influence the patient's ability to manage his or her chronic illness (Boxer & Snyder, 2009). Many studies have shown that communication of CKD is lacking in the primary care setting and often times relates to only discussing lab values with no understanding of the disease or individual risk (Couser et al., 2011; Greer et al., 2011; Taal, 2013).

The current evidence presents high to good quality interventions that influenced the development of the communication tool. Although most of the studies did not explicitly relate the self-management interventions to communication, a majority included at least one component of successful communication as described by Feldman-Stewart et al.'s (2005) communication framework. For example, according to Feldman-Stewart et al. (2005) the purpose of communication is to address the goals of the participants. This can be accomplished through goal-setting with the patient or developing collaborative treatment plans. Studies by Choi and Lee (2012), Chen et al. (2011), Hamilton et al. (1993), Naik et al. (2011), Rosal et al. (2011), Thoolen et al. (2009) and Teng et al. (2013) included either collaboration or goal-setting and all were successful in improving self-care or physiological outcomes. Subsequently, goal-setting is an important component of the communication tool. Furthermore, the most successful interventions were those that were individualized (Bosworth et al., 2009; Chen et al., 2011; Friedberg et al., 2013; Garcia et al., 2015; Garcia-Llana et al., 2013; Hamilton et al., 1993;

Johnson et al., 2006; Jones et al., 2003; Kim, Hwang, & Yoo, 2004; Naik et al., 2011; Ogedegbe et al., 2012; Park et al., 2013; Partapsingh, Maharaj, & Rawlins, 2013; Rosal et al., 2011; Ruppap, 2010; Teng et al., 2013; Thoolen et al., 2009), elicited collaboration or interaction with the patient and provider (Bosworth et al., 2009; Chen et al., 2011; Garcia et al., 2015; Friedberg et al., 2013; Merakou et al., 2015; Naik et al., 2011; Park et al., 2013; Rosal et al., 2011; Ruppap, 2010), were motivational or encouraging (Choi & Lee, 2012; Friedberg et al., 2015; Garcia et al., 2015; Jones et al., 2003; Kim, Hwang, & Yoo, 2004; Teng et al., 2013; Thoolen et al., 2009) and stimulated conversation regarding barriers in order to help the patient problem solve and/or plan for the future (Choi & Lee, 2012; Friedberg et al., 2015; Garcia-Llana et al., 2013; Hamilton et al., 1993; Jia et al., 2012; Merakou et al., 2015; Park et al., 2013; Thoolen et al., 2009). These common themes have been supported in other systematic reviews; interventions employing multiple strategies are also more successful than single interventions (Lepard et al., 2015; Teng et al., 2013) therefore it was important that the communication tool include these elements. In order to effectively use the tool, the provider must first identify the patient's readiness to change by utilizing the questionnaire in Appendix D. The patient can fill this out prior to the visit to help the provider determine which section of the communication checklist should be used. Within the communication tool, the studies that influenced the development of the communication point are cited within the footnote. Further discussion of the communication tool can be found in Chapter 5.

Proposed Use of Communication Tool

The communication tool, which can be found in Appendix E was developed in order to help stimulate more meaningful communication between patients with or at high risk of CKD

and their provider. It is organized as a checklist to ensure that all pertinent topics to help transition the patient to more active stages of change are addressed. Williams et al. (2012) found that a standardized motivational interviewing checklist can be feasibly added to a primary care visit and was effective in improving BP control. Additionally, since most of the studies that were successful in improving patient outcomes or self-care behaviors had interventions lasting anywhere from six months to a year, the tool is intended to be used during all routine follow-up visits (Bosworth et al., 2009; Chen et al., 2011; Garcia et al. 2015; Garcia-Llana et al., 2013; Jones et al., 2003; Friedberg et al., 2015; Ogedegbe et al., 2012; Partapsingh, Mahara, & Rawlins, 2013; Rosal et al., 2011; Teng et al., 2013). Based on the TTM, patients move through a series of stages while engaging in behavioral change making it important to consistently assess and intervene appropriately based on the individual's readiness to change (Fort et al., 2013). Furthermore, CKD is a multi-dimensional disease in which lifestyle and self-care behaviors evolve as the disease progresses (Teng et al., 2013). Patients at risk for the disease also require life-long management of co-morbidities such as DM and HTN in order to prevent or slow the development of CKD (McClellan, 2005; Reutens, 2013). Therefore, the tool should not just be used once but rather throughout the life of the patient while he or she is under the care of the provider. Studies that had less favorable outcomes also suggested that a longer intervention would likely be more effective in improving outcomes (Chen et al., 2011; Choi & Lee, 2012; Merakou et al., 2015; Park et al., 2013).

Summary

This chapter presented the results of the systematic review of 28 studies related to the communication processes that helped influence self-management and/or behavioral change in the

primary care or outpatient setting between providers and patients with or at high risk for developing CKD. All of the studies were of Level II or higher and a majority of the quality of evidence were of good or high quality. Only one study was considered as low quality evidence due to a greater than 20% attrition rate and insufficient sample size (Hamilton et al., 1993). It is evident based on the review that self-management interventions that include a multi-dimensional approach of education, motivation, individualized barrier identification, problem-solving, goal-setting and induced interaction or collaboration were more successful than usual care or standard education in improving outcomes related to CKD, DM and HTN. A communication tool was also developed and presented in this chapter. Chapter 5 includes a discussion of the results including gaps and limitations in the research, the development of the communication tool and implications for future practice.

CHAPTER V: DISCUSSION

CKD affects approximately 29 million individuals in the U.S. and is a growing global epidemic that contributes to poor patient outcomes and high healthcare expenditures (Ayanda, Abiodun, & Ajiboye, 2014; Boulware et al., 2009; Couser et al., 2011; McKercher et al., 2013). Despite these statistics, the literature search revealed a limited amount of studies testing self-management interventions directed towards individuals with CKD. Furthermore, there were no studies that tested the use of a communication tool. As previously discussed, the way providers communicate with patients can directly affect their ability to manage their disease (Boxer & Snyder, 2009). Effective communication is especially important in patients with CKD who are on average prescribed six to eight medications, have multiple comorbid diseases, are required to follow certain dietary and fluid restrictions and engage in aerobic exercise (Devraj & Wallace, 2013). At times, this can be very confusing and discouraging (Devraji & Wallace, 2013). Furthermore, patients often rely on the provider's expertise and guidance before engaging in self-management behaviors (Ben-Arye & Visser, 2012). In order to meet the CKD goals of Healthy People 2020, providers and patients need to communicate effectively in the primary care setting. The proposed communication tool hopes to bridge this gap.

Communication Tool

There were four recurrent themes identified among the most successful self-management interventions: 1) Individualized or tailored communication 2) Communication of barriers and problem-solving, 3) Communication that is encouraging and motivating and 4) Communication of goals. Previous systematic reviews have identified similar themes and found individualized strategies, motivation, barrier identification and goal-setting to be more successful than usual

care or standard education in improving outcomes or self-care behaviors (Boolen et al., 2014; Lepard et al., 2015). Previous research also suggests that patients with CKD want more information to help with decision making which can be achieved by stimulating conversation regarding perceived barriers (Welch et al., 2015). Therefore, it was important to ensure that these elements were translated into the communication tool. In addition to this, Feldman-Stewart et al.'s (2005) communication framework emphasizes the importance of identifying barriers and setting goals in order to communicate successfully. This further supports the need for a tool that includes barrier identification and goal setting.

The communication tool was developed as a guideline to stimulate more effective and purposeful communication between the patient and provider (Appendix E). Prior to using the tool, the patient's stage of change must be assessed using the questionnaire found in Appendix D. After identifying this, the provider will locate the individual's stage of change on the checklist which provides stage-specific goals and a checklist of communication points to ensure all topics are addressed. A study by Williams et al. (2012) used a standardized motivational interviewing checklist to guide the intervention and was successful in improving BP control. The communication points were organized by the stages of change developed by Prochaska and DiClemente (1983) and developed with influence of the common elements from the studies identified by the systematic review. CKD related strategies and complications were developed based on suggestions from the NKF (NKF, 2015). The providers are also prompted in each stage to relay encouraging and motivational statements based on the patient's 'stage needs'; encouragement and motivation have been successful in other studies (Choi & Lee, 2012;

Friedberg et al., 2015; Garcia et al., 2015; Jones et al., 2003; Kim, Hwang, & Yoo, 2004; Teng et al., 2013; Thoolen et al., 2009).

The communication tool is meant to help supplement the provider's knowledge of current CKD treatment guidelines. The TTM is based on the idea that individuals differ in their readiness to change and therefore strategies influencing change should match. Using the TTM as a framework for the communication tool allows providers to tailor communication that would be the most effective and accepted by the patient (Prochaska & DiClemente, 1983). For example, in the pre-contemplation section of the communication tool, the providers are prompted to enhance awareness of individual CKD risk and help the patient realize the need for change. If the provider focused on pushing the patient to engage in lifestyle changes when he or she is not ready, this can possibly result in resistance from the patient. Six of the seven studies using TTM as a framework were successful in improving the desired physiological or self-care outcomes (Chen et al., 2011; Friedberg et al., 2015; Johnson et al., 2006; Jones et al., 2003; Park, Chang, Kim, & Swak, 2013; Teng et al., 2013). In the study that did not find any statistically significant improvement in Hemoglobin A1C, there was an unexpected worsening of glycemic control among the intervention and control groups. The authors noted that patients who received the stage-matched intervention had a significantly less worsening of glycemic control and that economic hardships were likely the reason for the unexpected outcome (Partapsingh, Mahara, & Rawlins, 2013). Based on these findings, the use of the TTM in a communication tool has the potential to improve CKD-related outcomes. In the future, the effectiveness of the communication tool must be tested.

Gaps in Research

There are significant gaps in research regarding the communication of CKD information and self-management interventions in the primary care or outpatient setting. The systematic review revealed that there is a limited amount of studies directed towards CKD and those that included a hypertensive or diabetic population did not portray CKD as a potentially significant consequence of uncontrolled diabetes or hypertension (Bolen et al., 2014; Bosworth et al., 2009; Duke, Colagiuri, & Colagiuri, 2009; Friedberg et al., 2015; Garcia, Brown, Horner, Zuniga, & Arheart, 2015; Hamilton et al., 1993; Johnson et al., 2006; Jones et al., 2003; Kim, Hwang, & Yoo, 2004; Leopard, Joseph, Agne, & Cherington, 2015; Medical Advisory Secretariat, 2009; Merakou, Knithaki, Karageo, Pal et al., 2015; Ogedegbe et al., 2012; Park, Chang, Kim, & Swak, 2013; Partapsingh, Mahara, & Rawlins, 2013; Theodondis & Barbouni, 2015; Naik et al., 2011; Norris, Engelgau, & Narayan, 2001; Rosal et al., 2011; Thoolen, de Ridder, Bensing, Gorter, & Rutten, 2009; Ruppap, 2010). Additionally, a majority of the studies did not directly address communication as an important component of the self-management intervention; although a few did employ motivational interviewing as a technique (Garcia-Llana, Remor, del Peso, Celadilla, & Selgas, 2013; Ogedegbe et al., 2012; Williams, Mania, Walker, & Gorelik, 2012). Studies have identified that there is a lack of therapeutic communication strategies among the CKD population (Garcia-Llana et al., 2013). Moreover, no studies were identified that tested a communication tool. This lack of research limits the availability of effective methods that can be used by primary care providers in order to improve communication of CKD information and self-management interventions. This further defends the importance of developing new strategies such as the proposed communication tool. With the growing population of patients at risk of

CKD, it is vital that more research is developed and interventions tested in order to identify the most effective communication processes for reaching and supporting individuals in this population.

Limitations

There are some limitations to this systematic review. First, the articles were searched and analyzed by a single reviewer and not all of the studies pertaining to self-management or behavioral change strategies may have been identified. Additionally, the studies were limited in generalizability in that some focused on single populations such as Veterans (Naik et al., 2011) or nursing home residents (Park et al., 2013) or employed convenience sampling from a single center (Choi & Lee, 2012; Garcia et al., 2015; Garcia-Llana et al., 2013; Kim, Hwang, & Yoo, 2004; Merakou et al., 2015; Teng et al., 2013). This hinders the ability to identify which strategies would be most effective for the general population of CKD patients. Authors also found it difficult to recruit participants and although were powered for statistical significance had small sample sizes (Chen et al., 2011; Friedberg et al., 2015; Garcia et al., 2015; Garcia-Llana et al., 2013; Kim, Hwang, & Yoo, 2004; Jones et al., 2003; Naik et al., 2011; Ruppar, 2010; William et al., 2012). Small samples sizes can also limit the generalizability of the results. In studies that identified minimal to no statistical differences authors suggested that a longer follow-up is needed to fully realize the effects of the interventions (Chen et al., 2011; Choi & Lee, 2012; Merakou et al., 2015; Park et al., 2013; Teng et al., 2013). This same limitation was found in the systematic review of diabetes self-management interventions (Lepard et al., 2015). Furthermore, some studies used less rigorous designs in that allocation was not random (Garcia et al., 2015; Kim, Hwang, & Yoo, 2004; Jia et al., 2012; Johnson et al., 2006; Merakou et al.,

2015; Park et al., 2015). Future studies need larger sample sizes, longer follow-up, generalized populations and more rigorous research design to help fully realize the most effective evidence-based interventions.

Implications for the DNP and Clinical Practice

As health care leaders and providers to many patients who have or have the potential to develop CKD, the DNP plays an important role in ensuring that the most effective evidence-based interventions are used to slow or prevent the progression of the disease. Early intervention can improve outcomes among patients with CKD (Walker et al., 2013). This DNP project has made evident that further research is needed among this population of patients. Self-management is a dynamic process that requires not only education but collaboration, support and motivation which can easily be translated through effective communication (Lepard et al., 2015; Teng et al., 2013). Communication with the provider is a significant contributor to the way patients respond to self-management interventions and evidence is lacking in identifying the most effective therapeutic communication strategies (Boxer & Snyder, 2009; Garcia-Llana et al., 2013). With bedside and research knowledge the DNP can help influence the development of communication strategies that can be tested and implemented in clinical practice. The DNP can also help other providers recognize the importance of communication and influence a change in the way patients and providers interact in the primary care setting. Utilizing a standardized communication tool can help the DNP bridge this gap by identifying individual needs and stimulating more meaningful conversation with the patient that may not have happened without a standardized approach. The goals for *Healthy People 2020* are to reduce the prevalence of CKD and the healthcare disparities faced among this population (USDHHS, 2013). In order to do so,

individual risk must be properly communicated and primary care providers are key to the success of improving patient outcomes through early intervention and encouraging self-management behaviors.

Dissemination of DNP Project

Early identification and treatment of CKD can help slow the progression of the disease and improve long-term outcomes. Despite this, there continues to be a lack of communication especially in the early stages of the disease (Couser et al., 2011; Greer et al., 2011; Taal, 2013). Patients who have Medicare are also not eligible for insurance-paid kidney disease education until Stage IV chronic kidney disease (Medicare.gov, n.d.). This further supports the importance of this DNP project and communication tool as it hopes to stimulate discussion in the early stages in which interventions can be most effective in helping patients prolong the development or progression of the disease. This author hopes to disseminate this project through professional conferences and by publishing these findings. It is important to champion the need for early and effective communication of CKD among those at the highest risk for developing the disease.

Conclusion

The purpose of this DNP project is to help improve long-term outcomes among patients with CKD by enhancing the effectiveness of communication between the patient and provider in the primary care setting. Education alone is not sufficient to relay the pertinent information that patients with CKD need in order to slow or prevent the progression of the disease (Teng et al., 2013). In regards to the original research question, the systematic review revealed that there is a significant lack of therapeutic communication processes among the CKD population and there is a strong need for new communication processes. However, although communication was not

directly addressed, there were self-management interventions that were successful in improving patient outcomes and self-care behaviors, which can subsequently lead to benefits in preventing or slowing the progression of CKD; these studies influenced the development of the communication tool. Self-management interventions that were most successful in improving physiological outcomes or self-care behaviors were those that were individualized (Bosworth et al., 2009; Chen et al., 2011; Friedberg et al., 2013; Garcia et al., 2015; Garcia-Llana et al., 2013; Hamilton et al., 1993; Johnson et al., 2006; Jones et al., 2003; Kim, Hwang, & Yoo, 2004; Naik et al., 2011; Ogedegbe et al., 2012; Park et al., 2013; Partapsingh, Maharaj, & Rawlins, 2013; Rosal et al., 2011; Ruppap, 2010; Teng et al., 2013; Thoolen et al., 2009), motivating (Choi & Lee, 2012; Friedberg et al., 2015; Garcia et al., 2015; Jones et al., 2003; Kim, Hwang, & Yoo, 2004; Teng et al., 2013; Thoolen et al., 2009), included barrier identification and problem-solving (Choi & Lee, 2012; Friedberg et al., 2015; Garcia-Llana et al., 2013; Hamilton et al., 1993; Jia et al., 2012; Merakou et al., 2015; Park et al., 2013; Thoolen et al., 2009) and goal setting (Choi & Lee, 2012; Friedberg et al., 2015; Hamilton et al., 1993; Johnson et al., 2015; Naik et al., 2011; Park et al., 2013; Rosal et al., 2011; Teng et al., 2013; Thoolen et al., 2009). The communication tool influenced by the systemic review may be a beneficial strategy that can be implemented in future practice and simultaneously tested for effectiveness. As the CKD population continues to grow, it is crucial that providers change the way they communicate with their patients in order to stimulate positive self-care behaviors.

APPENDIX A:
DATA EXTRACTION TOOL

Title/Source of article		
Date of review:		
Notes		
Eligibility for review: [] humans, adults age 18 years and older, [] primary research studies, systematic and literature reviews, [] focus on CKD or chronic illness communication interventions to enhance patient outcomes and/or self-management behavior [] Availability of full-text online or by request		
Methods		
Study design:	Measures:	Blinding:
Participants		
Total number:	Setting:	Diagnostic criteria:
Age:	Sex:	Country:
Interventions		
Number of groups:	Type of Intervention (s):	
Outcomes/Results		
Include for each outcome: Outcome definition, unit of measure (if applicable), sample size, effect size		
Miscellaneous		
Key conclusions, strengths, weaknesses		

APPENDIX B:
FORMAT FOR SUMMARY OF FINDINGS TABLE

Source	Type of Study	Sample/Setting	Measures/Interventions	Outcomes/Effect sizes	Key conclusions/Recommendations	Risk Bias	Quality Rating

APPENDIX C:
SUMMARY OF FINDINGS TABLES

Author (s)	Type of Study	Sample/Setting	Measures/Intervention	Outcomes/Effect sizes	Key conclusions/ Recommendations	Risk Bias	Quality Rating
Williams, Mania, Walker & Gorelik (2012)	RCT	75 participants with co-morbid diabetes, CKD & HTN- Intervention group n=36. Mean age 65 years old, 56.3% male. Primary school 38.5% (intervention); 29.3% (control). Melbourne, Australia- Public tertiary metropolitan hospital outpatient clinic	Primary outcomes- Attrition rates and open-ended question assessing satisfaction. Secondary outcomes- BP control and medication adherence rate (pill counts) F/u 3, 6 and 9 months Intervention- Multifactorial with motivational interviewing (MI). Face-to-face individual medication review, DVD education and f/u telephone reinforcement every 2 weeks x 3 months. Structured MI checklist. Control- Standard care	No SD between groups. CS reduction in systolic BP in intervention group. - 6.9 mmHg decrease systolic BP (95% CI) in intervention group; -3.0 mmHg decrease systolic BP (95% CI) in control group. No difference in medication adherence between groups using pill counts. Mean adherence rate 66.0% (intervention) and 58.4% (control).	Greater reduction in systolic BP likely related to BP self-monitoring and aiming for specific BP targets. Participants enjoyed the supportive nature of f/u calls.	None	Level I/B
Partapsingh, Mahara & Rawlins (2013)	RCT	119 participants with Type 2 DM Intervention group n=61. Ages 40-59 years. Male 64% (intervention); 66% (control). Primary school education 67% (control); 57% (intervention). 34% in both groups diabetic for 5-10 years. Trinidad-Ste. Madeline Health Centre Outpatient Clinic	Primary outcome variable: HgbA1C Secondary outcome variable: Patient's readiness to change. Self-reported data. 48 weeks f/u. Intervention- Face-to-face stage-specific and personalized to patient as a whole. Providers used forms specific to SOC containing a checklist of items to address during each consultation. Consultation session was once every 16 weeks for 48 weeks. Control- Usual care- Monitoring weight, glucose, BP, discussing concerns with staff and refill medications.	Primary outcome: Intervention did not improve glycemic control (p=0.025); worsened for both groups. SD in glycemic control. HgbA1C mean increase 0.52% (SE 0.17) in intervention and 1.09% (SE 0.18) in control group. Secondary outcome: Increased readiness to change: 21 participants (intervention); 7 participants (control).	Economic hardship likely contributed to bilateral worsening of HgbA1C. SOC model does not fully address multiple behaviors involved in DM management. Although HgbA1C did not improve, there was less increase in intervention group which highlights some benefit of applying SOC concepts to DM management	Detection bias- PI provided care to both groups	Level I/B
Friedberg et al. (2015)	RCT	533 participants with hypertension. (3 groups) SMI-176, UC-177 and HEI 180 participants. Mean age 66.4 (SMI), 66.5 (HEI) and 65.4 years (UC). Men 98.9% (SMI), 99.4% (HEI) and 97.7% (UC). BP controlled 42.6% (SMI), 40.6% (HEI) and 44.6% (UC). NY, USA- Veterans Affairs Medical Center Clinics	BP control- SBP/DBP based on JNC 7 guidelines Secondary-Medication adherence (Morisky adherence scale)- score range 0-4; <4= non-adherence and Diet (Willett Food Frequency Questionnaire)- score range 8-40; high scores=higher adherence 6-month f/u. Stage-mediated intervention (SMI) (intervention 1). Tailored interactive 20-minute individual monthly phone counseling for exercise, diet and meds based on SOC. Non-tailored interactive health education (HEI) (intervention 2). Standard 15-minute individual monthly phone counseling for	SMI significantly lowered SBP in 6 months than UC (131.2 vs 134.7 p=0.009). HEI lowered mean SBP than UC (131.8 vs 134.7 p=0.047). 19.7% improved BP among those with controlled BP in SMI group (p <0.0001). 11.9% (p=0.012) and 1.3% (p=0.76) in HEI and UC respectively. Change in mean dietary approaches 0.69 in SMI, -0.16 in HEI, and -0.76 in UC (P values, SMI versus UC, 0.01; HEI versus UC, 0.32) No SD in Morisky scores	SMI is a valuable tool to help lower BP and improve control. Can be translated to other chronic conditions to help improve adherence and clinical outcomes.	None	Level I/A

			exercise, diet and meds.				
			Control- usual care (UC)				
Ogedegbe et al., 2012	RCT	256 hypertensive African American. Mean age (SD)- 58 (12) years. Women 77% (control); 82 % (intervention). 40% employed (control), 43% (intervention)Mean duration of HTN 11 years (control) and 12 years (intervention). Medication adherence score avg 1.2 (control) and 1.0 (intervention). NY- Ambulatory care setting	Primary outcome: Medication adherence- electronic pill count Secondary outcome: BP control based on JNC 7 guidelines 12-month follow-up Intervention: 2 groups Patient Education (PE) Control- Culturally tailored educational workbook Positive affect (PA) Intervention- Culturally tailored educational workbook with positive affect induction and self-affirmation. Individual telephone interviewing bi-monthly x 12 months.	Medication adherence significantly higher in PA than PE group (42% vs 36% respectively, p=0.049). No SD in BP reduction. SBP 2.14 mm Hg for the PA group vs 2.18 mm Hg for the PE group; P = .98).	A combination of patient education and motivational interviewing can improve medication adherence among African Americans Adaptation of intervention can be practical in primary care settings	None	Level I/A
Thoolen, de Ridder, Bensing, Gorter & Rutten, 2009	Multi-center RCT	180 participants, newly diagnosed Type 2 diabetes. Mean age (SD) 62.0 (4.9) in intervention group and 61.9 (5.6) in control group. Male 64 % (intervention) and 55% control. Mean duration of disease (SD) 18.4 (8.8) months in intervention group and 17.0 (9.0) months in control group. Netherlands- Outpatient setting	12 item self-efficacy questionnaire- higher score= higher self-efficacy (Cronbach α -0.84. Intensions- Six-item questionnaire. Higher score=higher intensions. Diabetes Self Care Activities (DSCA) Measures- 10-items- Mean scores 0-7. High scores indicate higher level of self-care (Cronbach α 0.94), Dietary scale (Cronbach α 0.94), exercise scale (Cronbach α 0.97), medication scale (Cronbach α 0.90). Proactive Competence Inventory- 12-item score ranging from 1-4. Higher score=higher proactive competence (Cronbach α 0.86). Physical Activity Scale for Elderly- 15-item, score 0-800. Kristal Food Habits questionnaire- 20-item, 4-point Likert scale (Cronbach α 0.92). Higher score= higher level of fat intake. Self-management course- 2 individual sessions (experiences, evaluation of goals and future planning) and 4, 2-hour group sessions (goal setting related to diet, meds and exercise). Control- Usual care 12 week and 9 month follow-up.	Intervention group significantly better on all self-care measures except for medications at 12 weeks and 9 months (np ² - 0.02-0.10). Significant and moderate improvements in proactive competence (2.9 to 3.1 (12 weeks) to 3.2 (9 months), p<0.01 vs 2.9 to 3.0 to 3.0 in control) proactive behavior (2.6 to 3.1 (12 weeks) to 3.0 (9 months), p<0.01 vs 2.6 to 2.6 to 2.5 in control) and goal attainment (5.4 to 6.7 (12 weeks) to 6.8 (9 months), p<0.01 vs 6.1 to 6.0 to 5.9 in control). Proactive competence significant predictor of long-term self-care (p<0.01).	Intervention group had higher goal attainment and more confidence in ability to self-manage. Developing achievable goals and evaluating success is key to sustained behavioral change. Proactive coping is a significant predictor of long-term self-management and may benefit other chronic conditions.	Attrition bias- >5% dropped out (16 in total). Non-response study indicated only education differed in non-participants and dropouts. Recall bias- self-reported measures	Level I/A
Welch, Johnson, Zimmerman,	Lit Review	7 articles testing self-management interventions in Stage 1-4 CKD patients.	Evaluate types of self-management interventions, methods to test interventions and outcomes of interventions related to a	All included knowledge development as main component. No evidence of decision making, resource utilization	Education content incomplete.	None	Level III/B

Russell, Perkins & Decker, 2015		Sample size 30-81 Mean age 57.5-67 years old. 52%-69% Male, Total duration of intervention single session – 6 months.	range of measures including eGFR, med adherence, BP control, diet and exercise and glycemic control. Mixed RCTs and quasi-experimental designs.	or self-tailoring. No significant improvement in eGFR. Three studies tested self-efficacy, 2 showed significant improvements ($p<0.1$, $p<0.5$). BP (4 studies) 1 showed improvement in BP; no statistical significance reported. Self-management (2- significant improvement, $p<0.001$, 2 no SD. Med adherence (2- improvement in 1 study, no report of stats; no SD in other). Diet and exercise (1 study; significant improvement, $p<0.5$). Glycemic control (1 study; significant improvement $p<0.05$).	Future interventions should consider acquisition of knowledge, development of self-management skills, enhance confidence and utilize patient activation strategies. Need messages to support decision making. Unable to form adequate conclusions regarding the effectiveness of the interventions due to insufficient methodological rigor		
Park, Chang, Kim & Swak (2013)	Non-equivalent comparison group	N=47, older adults with hypertension Mean age 77.4 years old. Disease duration 12.5 years, 34% female, 44 % 12 th grade education or less. 36 took meds without assistance Korea-Nursing home	Primary outcome- BP (SBP/DBP) based on JNC 7 guidelines Secondary outcomes-Scale of self-care behavior of HTN- 20-item, total score range 20-100. Higher score= higher level of self-care (Cronbach α 0.77). Self-efficacy for Exercise- 8-item, score range 10-100 (Cronbach α 0.96), higher score=more confidence. Non-adherence questionnaire- 4-item, one answer of yes was non-adherent 8-week follow-up. Once a week for 8 weeks- 60-minute face-to-face group health education sessions (group discussions and personal experiences) and tailored 30-minute one-on-one individualized counseling focused on barrier identification and strategic planning.	Patient-tailored self-management significantly reduced SBP 127.6 mmHg to 120 mmHg at 8 weeks, $p=0.069$ versus 130.9 mmHg to 132.8 mmHg, $p=0.120$. All other areas improved significantly except for medication adherence. Self-care behavior significantly increased by +13.7 points, $p=0.000$ while control group had a significant worsening of self-care by -3.4 points $p=0.001$.	Self-management interventions should be tailored to individual needs and cultural circumstance. Tailored intervention beneficial for reducing BP at clinically significant level and improving self-care behavior and exercise self-efficacy.	Selection bias- non-random sample	Level II/A

Teng, Yen, Fetzer, Sung & Hung (2013)	RCT	<p>N=160, adults with CKD (2 groups)</p> <p>Mean age 63.9 years, 71% male, 74% with moderate declines in GFR. Mean GFR 51.7 ml/min.</p> <p>Taiwan- Four outpatient nephrology clinics</p>	<p>Health promoting lifestyle profile- IIC (HPLC-IIC) 52-item Questionnaire – 4-point Likert scale. Higher scores more health-promoting behaviors (Cronbach α (0.66 to 0.85), Renal Protection Knowledge Checklist (RPK)- scores 0-100. Higher scores=greater knowledge. (Kuder-Richardson formula 20, 0.43-0.54), eGFR (Modification of Diet in Renal Disease [MDRD] formula) and physical indicators (BMI, WHR)</p> <p>3, 6, 9, 12- month follow-up</p> <p>Face-to-face individual standard intervention with stage-matched exercise and dietary consultation. Intervention included problem-solving, goal setting and encouragement.</p>	<p>Significant effect in HPLP-IIC scores of health responsibility ($\chi^2=13.63$, $p=0.001$), physical activity ($\chi^2=7.50$, $p=0.01$) but no SD in stress management, interpersonal relations, spiritual growth or nutrition. SD in lifestyle behavioral change ($\chi^2=19.66$, $p=0.001$). Intervention had upward trend in RPK ($p=0.001$), control did not. Physical indicators- no SD. 60% in intervention moved from non-action to action stages compared to 13% in control.</p>	<p>Stage-matched intervention improved stages of change in diet and RPK for CKD.</p> <p>Longer follow-up may be able to identify true effect of targeted interventions on GFR and physical indicators.</p> <p>It is important to assess individual readiness to change and develop interventions to match.</p>	<p>Recall bias- self-reported measures</p> <p>Measurement bias- Cronbach α <0.70</p>	Level I/B
Kim, Hwang & Yoo (2004)	Non-random Quasi-experiment	<p>N=45, Korean Type 2 diabetics (2 groups).</p> <p>Mean age 53.29 years, 62.2% male, mean duration of DM 7.39 years, mean HgbA1C 7.84 (intervention), 7.78 (control)</p> <p>Korea- Outpatient diabetic clinic</p>	<p>Stages of readiness exercise behavior scale (SOC)- statements matched criterion based on TTM (Kappa index=0.78), 7-day physical activity questionnaire- self-reported recall of time and intensity of activity, fasting blood sugar (FBS) and HgbA1C</p> <p>12-week follow-up</p> <p>Individual face-to-face stage-matched counseling, behavior training (one 60-90-minute session) plus twice a week 10-30-minute telephone counseling with positive reinforcement and problem-solving for 3 months.</p>	<p>Significant increase in overall SOC ($t=-3.53$, $p<0.001$) and physical activity level ($t=-4.78$, $p<0.001$). 77.4% progressed in intervention compared to 4.3% in control. Physical activity significantly increased (intervention)($p=0.000$), no SD in control. Significant reductions in FBS 156.32 to 139.14 (intervention) versus 153.74 to 164.35, $p=0.03$ (control) & A1C 7.84% to 6.96% versus 7.78% to 8.19%, $p=0.02$.</p>	<p>SMI improved SOC for exercise behavior and physical activity and decreased FBS & HgbA1C.</p> <p>Stage-matched interventions decrease likelihood of individual to stop participating.</p> <p>Evidence suggests there is potential benefit of SMI for diabetic patients.</p> <p>Future studies need to assess its effects in other settings.</p>	<p>Selection bias- non-random sampling</p> <p>Recall bias- self-reported measure of physical activity</p>	Level II/B
Garcia-Llana, Remor, del Peso, Celadilla & Selgas (2013)	Non-random quasi-experiment	<p>N=42, Advanced CKD patients (no control).</p> <p>Mean age 64 years, 60% male, 50% primary school highest completed education, 100% had CKD and HTN.</p> <p>Spain- Outpatient clinic</p>	<p>Survey of adherence to treatment (Cronbach α- 0.62), Morisky-Green-Levine test to test med adherence to oral meds (Cronbach α- 0.52), Stages of Behavior Change related to oral medication compliance assessment scale (Cronbach α- 0.60), Beck Depression Inventory (Cronbach alpha- 0.91), State-Trait anxiety inventory (Cronbach α- 0.52), Short form 36 Health Survey, version 2 (Cronbach α- 0.56-0.97).</p> <p>Secondary measures: Creatinine clearance,</p>	<p>More reported better adherence to treatment on Adherence to Treatment Survey (Mean score 27.12 pre and 31.35 post, $p<0.001$) and Morisky-Green-Levine test ($\chi^2=3.36$, $p<0.001$). Participants in action stage increased from 39% to 60%. 93% of participants reached their motivational diagnosis target ($p<0.001$). All biological markers were better controlled after intervention except for iPTH.</p>	<p>Intervention based on SOC & motivational interviewing is effective in promoting adherence.</p> <p>Can be feasibly applied in primary care setting.</p>	<p>Selection bias-non-random sampling</p> <p>Measurement bias- Some measurements had Cronbach alpha <0.70. Low reliability</p>	Level II/B

			albumin, hemoglobin, potassium, calcium, phosphate, iPTH 6-month follow-up. Six, monthly 90-min individual face-to-face session skills training with motivational interviewing.				
Johnson et al. (2006)	RCT	N=1227 participants enrolled in health maintenance organization with HTN (two groups) Mean age 55.7 years. New-England- home-based intervention	Non-adherence measure, 5-item, 5-point Likert (Cronbach α 0.67), lower scores= greater adherence. Stage of Change Algorithm based on TTM 3, 6, 12 and 18-months follow-up Pro-Change Program for high blood pressure medication- Stage-matched, individualized written manual plus computer generated feedback report at 3 and 6 months. Control –Usual care	Significantly more individuals in treatment group were in action or maintenance stage at 12 months (73.1% versus 57.6%, $p<0.001$) and 18 months (69.1% versus 59.2%, $p<0.01$). Significantly lower non-adherence rate at 12 months ($p<0.01$) and 18 months ($p<0.001$).	TTM-based computerized intervention had significant effect on adherence to anti-hypertensive medication Potential for significant impact on other chronic conditions Can be feasibly implemented in primary care setting	None	Level I/A
Bosworth et al. (2009)	RCT	N=636 adults with HTN for at least 12 months (4 groups) Mean age 61 years, 49% African American, 66% female, 19% reported inadequate incomes. Baseline BP 125/71 USA- Two outpatient primary care clinics	BP control based on JNC 7, SBP/DBP 6, 12, 18, 24-months follow-up Group 1- Usual Care Group 2- Tailored bi-monthly individual behavioral phone intervention only Group 3- Home BP monitoring three times a week on three separate days at the same time of day. Mailed logs every 2 months. Group 4- Combination (behavioral phone intervention, bi-monthly) + home BP monitoring) Intervention lasted for 2 years.	Combined group significant improvement in BP control compared to usual care 11.0% improvement BP control (95% CI: 1.9% 19.89%, $p=0.012$). Behavioral 4.3% improvement BP control (95% CI: -4.5%, 12.9%, $p=0.34$) vs Home BP 7.6% improvement BP control (95% CI: -1.9%, 17%, $p=0.096$). 24 months mean SBP and DBP significantly lower only in combined group (-3.9 mmHg, 95% CI: -6.9%, -0.9, $=0.010$; -2.2 mmHg, 95% CI: -3.82%, -0.6%, $p=0.009$ respectively)	Individualized behavioral intervention and home BP monitoring resulted in clinically significant improvement in BP control after 24 months. May be a valuable tool for improving BP control.	None	Level I/A
Chen et al. (2011)	RCT	N=54, pre-dialysis adult CKD patients (2 groups) Avg age 68.2 years, 55.6% male, 70.4% Junior high education or less, 67.3% CKD Stage III-IV, mean eGFR 25.38 ml/min Taiwan- outpatient clinic	CKD knowledge checklist (Cronbach alpha, 0.80), eGFR and hospitalization rates 6 and 12-month follow-up. Self-management support- health management information, patient education, weekly telephone-based support and support group. Monthly (12 months) face-to-face individualized education sessions were based on patient needs.	SMS significantly improved CKD knowledge after 12 months (+10.3 points (SMS); +5.51 points (usual care), $p<0.001$). eGFR significantly higher in SMS (29.11 ml/min, $P <0.05$). Hospitalization significantly lower ($n=5$ (SMS), $n=12$ (usual care), $p<0.05$).	Standardized SMS intervention effectively slowed renal progression and reduced morbidity among late-stage CKD patients. CKD knowledge plays significant role in slowing progression.	Unclear- No discussion of randomization, blinding or sample size calculation	Level I/B

					SMS may help improve patient-provider relationship and lead to patients embracing CKD treatment.		
Naik et al. (2011)	RCT	<p>N=87 Adult Veterans with Type 2 DM (2 groups)</p> <p>Mean age 63.82 years, 31% at least some college, mean years with DM 4.98 years & mean HgbA1C 8.86% (intervention); Mean age 63.45 years, 31% at least some college, 5.04 years (mean) with DM, Mean HgbA1C 8.74% (control).</p> <p>Houston- 2 outpatient primary care clinics</p>	<p>HgbA1C & 8-item Diabetes Self-Efficacy Scale, 10 point Likert Scale. Higher score=higher self-efficacy. Scores range from 0-10.</p> <p>3-months and 1-year follow-up. Control- Traditional group education sessions and usual care by PCP. 2, 2-hour groups sessions and 2, 20-30-minute consultation with PCP following group sessions.</p> <p>Intervention- Empowering patients in care (EPIC); goal setting and action planning/evaluation in face-to-face group clinic. 4 group sessions- 1-hour group interaction and 10-minute individualized consultation follow group session.</p>	<p>EPIC significantly greater improvement in HgbA1C mean (SD) between group difference 0.67% (1.3%) p=0.03 three months post intervention. Improvement persisted at 1-year follow-up (0.59% (1.4%), p=0.05). However, no growth in improvement after 1 year. Self-efficacy measures at 3 months significantly higher in EPIC (mean group difference, 0.84, p=0.02).</p>	<p>Clinically significant improvement in HgbA1C is achievable with EPIC approach for self-management.</p> <p>Highlights importance of goal setting and implementation of behavior change.</p> <p>Booster sessions may have produced additional improvements in HgbA1C.</p>	None	Level I/B
Rosal et al., (2011)	RCT	<p>N=252 Latino adults with Type 2 DM (2 groups)</p> <p>32.9% age between 55-64 years old, 76.9% female, 31.3% 0-5 years since DM diagnosis. Mean baseline HgbA1C 9.0%.</p> <p>Massachusetts- Outpatient community health center</p>	<p>Primary- HgbA1C</p> <p>Secondary- diet, physical activity, blood glucose monitoring, self-efficacy (random 24-hr recall), lipids, BP and weight. Audit of Diabetes Knowledge. Higher score=higher knowledge. 17-item tool to assess self-efficacy for diet and physical activity (Cronbach α 0.85).</p> <p>4 and 12-month follow-up.</p> <p>Latinos en Control- Culturally-tailored education with brief personalized counseling, goal setting and problem solving. 12 weekly face-to-face sessions with first hour of personal consultation and then group sessions. After 12 weeks, 8 monthly f/u sessions.</p> <p>Control- usual care</p>	<p>HgbA1C <7% at 4 months 29.1% vs. 12.4% in intervention vs. control respectively (p=0.013), 12 months 23% vs. 16.2% (p=0.233). Significant improvement in dietary quality (p<0.01) at 4 and 12 months.</p> <p>No significant improvements in activity, lipid, BP, weight or waist circumference.</p> <p>Increased blood glucose self-monitoring at least twice a day- 59% baseline, 84.2% 4 months, 81.5% 12 months vs 55.7% baseline to 62.1% 4 months to 63.6% at 12 months in control group (p=0.02;4 months); (p=0.023;12 months).</p>	<p>Literacy and culturally-tailored intervention can result in clinically important short-term improvements in glucose control.</p> <p>Future studies needed to develop strategies to sustain improvements.</p>	Recall bias- self-reported measures	Level I/A

Choi & Lee (2012)	Nonequivalent control group, non-synchronized design	<p>N=61 adults with CKD (2 groups)</p> <p>67.7% male, 41.9% \geq60 years, 38.7% high school education and mean GFR 38.60 ml/min (intervention group); 70.0% male, 50% \geq60 years, 43.3% high school education, mean GFR 43.93 ml/min (control)</p> <p>Korea- Outpatient clinic</p>	<p>Knowledge of Chronic Kidney Disease Scale- higher score= more knowledge (Cronbach alpha, 0.81), Self-care Practice Scale for CKD patients- 5-point likert scale. Higher score=higher self-care. (Cronbach alpha 0.88).</p> <p>Physiological factors- BUN/Cr, sodium, potassium, calcium, phosphate, Hgb and GFR (MDRD)</p> <p>4 and 8-week follow-up.</p> <p>Multi-dimensional face-to-face group education with individualized consultation and reinforcement focused on self-management behavior, diet and disease progression.</p>	<p>Knowledge about CKD in intervention significantly improved overtime compared to control (Baseline to 4 weeks and 8 weeks- 10.32 to 14.22 to 15.41 compared to 11.13 to 11.50 to 11.40, $p<0.001$). Self-care practice scale scores significantly increased in intervention compared to control (3.55 to 3.88 at 8 weeks compared to 3.79 to 3.85 in control $p=0.001$). No significant improvement in physiological indicators of kidney function.</p>	<p>Face-to-face self-management intervention resulted in improvement in knowledge of CKD and self-care practice.</p> <p>PCPs should identify patient needs and provide consultation accordingly.</p> <p>Longer follow-up to fully realize effects on physiological indicators of kidney function.</p>	Selection bias-non-random assignment	Level II/B
Garcia, Brown, Horner, Zuniga & Arheart (2015)	RCT	<p>N= 72 Mexican American adults with Type 2 DM</p> <p>Mean age 49.6, 67% female, 45% Spanish speaking, median 3 years diagnosed with DM, avg 14 symptoms over last week.</p> <p>Texas- Rural community</p>	<p>Primary outcomes- HgbA1C, lipid control-venous blood sampling, BP (SBP/DBP), BMI & 38-item Diabetes Symptom Self-care inventory- 4-point Likert. Higher scores=higher severity of symptoms</p> <p>Secondary outcomes- Spoken Knowledge in Low Literacy in Diabetes Scale (SKILLD)- 10-item, higher score=more knowledge, Diabetes-39 (QOL), scores 0-100 higher score=higher impact of diabetes on quality of life (Cronbach α 0.96), Perceived Diabetes Self-Management Scale (PDSMS)- 8-item, score range 8-40. Higher scores=more confidence in diabetes self-management. Diabetes Empowerment Scale (DES)- 8-item, 5-point Likert. Higher scores=greater psychosocial self-efficacy to manage diabetes (Cronbach α 0.80).</p> <p>2 and 6-month follow-up</p> <p>Intervention- Symptom-based diabetes self-management education program (DSME)- Tailored based on symptoms, problem-solving. 8 weekly in home face-to-face education and behavioral modification and 8 biweekly support via telephone.</p>	<p>Intervention group demonstrated significant decrease in HgbA1C at 2 months compared to control (8.6% to 7.8%, $p<0.001$).</p> <p>No significant change in SBP, triglycerides or BMI.</p> <p>Significant group by-time interaction effects on improvement in # of symptoms, symptom severity, diabetes knowledge, self-efficacy and empowerment.</p>	<p>DSME resulted in statistically significant, clinically meaningful and psychological benefits to participants.</p> <p>Participants reported that visits and follow-up phone calls motivated them to improve glucose control.</p> <p>Clinically significant improvement in HgbA1C at 2 months, not sustained at 6 months.</p> <p>Assessing over longer time may help see actual benefits of intervention on HgbA1C.</p>	Attrition bias-sample at 6 months was smaller than anticipated at six months; inadequate power to detect difference in HgbA1C, may have inflated results during 6-month follow-up	Level I/B

			Control- Usual care and education from PCP. After 6 months, were offered home intervention.				
Merakou, Knithaki, Karageorgos, Theodoridis & Barbouni (2015)	Controlled clinical trial	N=193 adults with Type 2 DM (2 groups) Mean age 63.8 years, 58.2% male, 69.1% primary/high school education, mean years with DM 9.5, Mean HgbA1C 8.2% (intervention). Mean age 67.2 years, 53.6% male, 81.9% primary/high school education, mean years with DM 7.7, mean HgbA1C 6.9% (control) Greece- Primary care clinic	HgbA1C, BMI, triglycerides, HDL & LDL- venous blood sample 6-month follow-up Intervention- 3 weeks- 2-hour once a week structured group patient education using conversation maps (CM) (3 sessions). Included group discussions, questions and answers and scenarios. Control- Standard individual education	HgbA1C statistically improved in both groups but improved more in intervention compared to control (-0.6 (95% CI: -0.8, -0.3, p<0.001) vs. -0.5 (95% CI: -0.5, -0.3 p=0.003). No SD in BMI. BMI decreased significantly in intervention group avg change -0.7 (95% CI: -0.9, -0.1, p=0.007). Intervention statistically significant decrease in triglycerides (p=0.003) and LDL (p=0.001). HDL (p=0.001) and LDL (p=0.018) decreased significantly in control.	Although both groups showed statistically significant results, differences were more favorable towards CM. CM is more effective compared with individual education in diabetes self-management	Selection bias- allocation was not concealed	Level II/A
Duke, Colagiuri & Colagiuri (2009)	SR/meta-analysis	N= 1359 participants with Type 2 DM between 9 studies (2 groups) Mean age between 52-65 years, 3 studies with mean years diagnosed with DM >7 years, 4 studies with mean years diagnosed with DM <3 years. Mean HgbA1C between 6.6-12.2%. Outpatient clinics	Primary outcome- HgbA1C Secondary outcomes- BMI, lipid control, DM knowledge, self-care behaviors. 6 to 9-month follow-up, 12 to 18-month follow-up or >18-month follow-up RCTs reviewed compared individual education vs usual care or individual education vs group education.	No statistically significant improvement in glycemic control compared to usual care and group education (weight mean difference (WMD) in HgbA1C -0.19% (95% CI: -0.3 to 0.1, p=0.33); 0.03% (95% CI: -0.22 to 0.1, P=0.22 respectively). Significant benefit of individual education on glycemic control in 3 studies with higher mean baseline HgbA1C >8% (WMD -0.3% (95% CI: -0.5 to -0.1, p=0.007)). No SD in BMI or lipid control compared to usual care and group education. Unable to complete meta-analysis for psychosocial outcomes.	Unable to make firm conclusions regarding individual education vs usual care and group education d/t limitations of studies. There are benefits of individual education in lowering HgbA1C in patients with poorer control. Further higher quality research is needed	None	Level I/A
Bolen et al. (2014)	SR, meta-analysis, meta-regression	N=33,124 adult participants with Type 2 DM between 138 studies Weighted mean (WM) age 59 years, WM baseline BMI 33 kg/m ² , WM baseline A1C 8.1%, WM SBP 140 mmHg. WM duration of DM 10 years. Primary care/outpatient clinics	Primary outcomes-A1C, SBP, BMI and lipid control Mean follow-up 12 months. Reviewed RCTs focused on enhancing patient activation (i.e. problem solving, audit & feedback, skill building, etc.)	Audit & feedback, skill building, psych-based counseling & individualized care plans had large unadjusted effect. Higher baseline A1C (B) -0.11, CI -0.19, -0.2, longer duration (B) -0.01 per month, CI -0.01 to 0.00 and pharmacist-led intervention (B) -0.50, CI -0.85 to -0.15 was associated with larger between group differences in A1C. Range WM difference (-0.25% to -0.44%) change in A1C. No single strategy significantly outperformed other.	PA resulted in model improvement in A1C without increasing short-term mortality. Studies with longer duration had larger improvements in A1C. Actively engaging adults with uncontrolled DM in self-management likely have a strong cumulative impact on morbidity/mortality	None	Level I/A

Hamilton et al. (1993)	RCT	<p>N=34 adults with primary hypertension (2 groups)</p> <p>Mean age 56.6 years (special intervention (SI), 51.7 years (standard treatment (ST), mean baseline BP 157/95 mmHg (SI) vs 144/88.7 (ST). SI mean history of BP 11 years, ST 12.7 years.</p> <p>Massachusetts- Outpatient clinic</p>	<p>Primary outcomes- SBP and DBP difference scores, appointment keeping, Instrument for Measuring Adherence- 6-item, 6-point Likert (Cronbach α 0.95), higher scores= higher level of adherence.</p> <p>F/u 6 months</p> <p>Special intervention- One 30-40 minute face-to-face tailored individual intervention with nurse practitioner based on standardized questionnaire-reinforcement of medical regimen, individualized negotiated plan of care, written and 12-minute video education, and problem-solving. Session occurred before regular PCP f/u visit. F/u phone call one month later to evaluate negotiated plan.</p> <p>Control- Usual care</p>	<p>Significant difference between groups in % of appointments kept (97.6% (SI) vs 73.53% (ST), $t=4.95$, $p=0.02$).</p> <p>Difference in scores of mean SBP significantly greater for SI group, -43 difference (intervention) vs -19, $p=0.02$).</p> <p>No SD in self-reported adherence however mean score adherence was higher in intervention group (.38 versus .25).</p>	<p>Results suggest that the special intervention may help increase adherence in patients with hypertension and improve SBP.</p> <p>Intervention is cost-effective.</p> <p>Longer follow-up should be tested to assess long-term benefits.</p>	<p>Response and Recall bias- self-reported adherence measure.</p> <p>Attrition bias- Attrition rate >20% in control</p>	Level I/C
Ruppar (2010)	RCT	<p>N=15 older adults with uncontrolled hypertension (2 groups)</p> <p>Age range 60-87 years, 73% female, 60% White. Took avg 5.8 daily prescription pills and 2.93 OTC.</p> <p>2 Midwestern Cities- Patient homes</p>	<p>Medication adherence (MA), SBP/DBP per American Heart Association Guidelines</p> <p>F/u 12 and 20 weeks</p> <p>Usual care + education materials.</p> <p>Intervention- Four home visits over eight weeks with standardized individual face-to-face MA and BP feedback, habit modification (individualized) and written medication and hypertension education materials.</p>	<p>Treatment group median improvement in MA of 15.4% vs -5.6% in control ($U=2.00$, $P=0.003$).</p> <p>SBP lowered to 130 mmHg at 12 weeks for intervention. Control group increased SBP to 152 mmHg.</p> <p>At 12 months, 8 of 10 participants in intervention group had controlled SBP, none in control group ($P=0.007$, Fisher exact test).</p>	<p>Pilot study- not powered for statistical significance</p> <p>Results suggest that behavioral feedback may be effective in improving MA and subsequently BP control.</p> <p>May need booster or longer follow-up to further improve outcomes.</p>	None	Level I/B
Jones et al. (2003)	RCT	<p>N=1029 adult patients with Type 1 or Type 2 diabetes (4 groups)</p> <p>Mean age 54.58 years (intervention 1), 55.12 (intervention 2), 54.86 (control 1) & 54.60 (control 2). 52.4% male, Mean duration with DM 10.09 years (intervention 1), 10.43 (intervention 2), 11.15 (control 1) & 10.24</p>	<p>Stages of Change- single-item staging algorithm based on intention related to healthy eating, self-monitor blood glucose and smoking, HgbA1C & Dietary intake (NCI Block)</p> <p>F/u 3, 6, 9 & 12 months</p> <p>Intervention- Pathway to change (PTC)- Stage-matched personalized assessment reports, self-help, individual phone counseling. Interventions provided were specifically related to participant needs</p>	<p>Significant treatment effect between PTC vs TAU ($p<0.001$). PTC alone and PTC with free strips results in increase % of participants moving to action and maintenance stages. PTC (healthy eating focus) moved more to action/maintenance vs TAU ($p<0.001$). 11.4% at maintenance vs 0% TAU ($X^2=26.52$, $p<0.001$). More quit smoking 17.8% action, 5.5% maintenance (PTC) vs 11.5% action % 0% maintenance ($X^2=7.01$, $p=0.02$). Only PTC participants increased SMBG frequency compared to decrease in control ($P<0.002$).</p>	<p>Access to supplies impacted frequency of SMBG.</p> <p>PTC significantly better than TAU in helping individuals move into action and maintenance states of critical diabetes self-care measures.</p> <p>Intervention has the potential to positively impact overall health.</p>	Recall bias- self-reported dietary adherence	Level I/B

		(control 2). Canada- Patient homes	and included either self-monitoring blood glucose (SMBG), healthy eating or smoking cessation or combination. Monthly contact x 12 months. Control and Intervention further randomized in to two groups- PTC, PTC +free glucose strips, Treatment as usual (TAU), and TAU +free glucose strips.	No SD in A1C. Those in action stage of SMBG and healthy eating, A1C significantly decreased P<0.001	Intervention has a capacity to deliver effective interventions to a large amount of people.		
Norris, Engelgau & Narayan (2001).	SR	84 articles reviewed that were focused on self-management training in adults with Type 2 diabetes Mean age ranged from 33-86 years old. No other population descriptions specifically discussed. Various settings	Primary outcomes- Knowledge, self-care, life-style behaviors, psychological outcomes and glycemic control. F/u ranged from 1 week to 2 years. Interventions reviewed were RCTs of self-management training with education focused on information, life-style behaviors, mechanical or coping skills. Multi-component interventions also included.	Regular reinforcement or repetition improved knowledge. Those focused on self-care showed no significant improvement in A1C. 2 studies failed to show improvement in diet, 3 studies showed improved physical activity; five showed no change. Mostly positive effects related to self-care. 4 studies showed improvement in problem-solving. 14 studies showed improvement in glucose control intervention	For knowledge and information interventions- method of delivery was directly related to glycemic control. Compared to didactic intervention, collaborative interventions proved somewhat more favorable results. Collaborative interventions focusing on knowledge tend to demonstrate positive effects on glycemic control in short term. Longer follow-up needed.	None	Level I/A
Medical Advisory Secretariat (2009)	SR/ meta-analysis	12 studies reviewed that were focused on behavioral interventions for adults with Type 2 DM Mean age 58 years, mean duration of diabetes diagnosis 6 years. 67% female. Primary care clinics, community, diabetes clinic	Primary outcome- Glycemic control (A1C). Median f/u 12 months. Longest was 8 years. Interventions: RCTs of multi-faceted behavioral interventions. Most focused on problem solving, goal setting, and encouraging patients to engage in activities to promote health.	Moderate but significant reduction in A1C -0.44% 95% CI -0.60, -0.29 (intervention) vs usual care. Individual sessions showed greater effect than groups sessions (-0.80, 95% CI -1.35, -0.25; -0.47, 95% CI -0.66, -0.28 respectively. Larger effects noted in interventions with least duration and in diabetics with higher baseline A1C >9% (-0.79 95% CI -1.23, -0.34) vs -0.40 95% CI -0.55, -0.24 with baseline A1C <9%.	Results suggest that behavioral interventions are effective in improving glycemic control among Type 2 diabetics. Shorter duration of intervention showed largest effects.	None	Level I/A
Jia, Bi, Lindholm & Wang (2012)	Retro-spective Study	N= 302 adults with CKD Stage 3, 4, & 5 (2 groups). S-MIP (short-term education) mean age 65 years, 50.7% female, 28.4% diabetic, mean eGFR 38 ml/min. L-MIP (long-term education) mean age 65 years, 50% female, 24.8% diabetic, mean eGFR 37	BP control (SBP/DBP), eGFR Intervention- Multi-dimensional education program. Face-to-face education, skills coaching and motivational activities (group discussions, story-telling & problem solving). Groups:	L-MIP associated with significantly lower SBP [128 mmHg versus 131 mmHg, p=0.05] and DBP (72 mmHg versus 77 mmHg, p=0.03). Decline of eGFR significantly faster in low education compared to high education (p=0.0334). No SD in BMI, hemoglobin, serum albumin and life-style related factors.	Multi-dimensional education program found to have positive effect on preventing or delaying progression of kidney function. Combination of knowledge, skill and encouragement may help achieve better BP control.	None	Level III/A

		ml/min Outpatient clinic	S-MIP- less hours of education L-MIP- more hours of education				
Lepard, Joseph, Agne & Cherrington (2015)	SR	Reviewed 15 studies related to diabetes self-management education (DSME) to adults with Type 2 DM Did not provide detail of patient characteristics Rural community	Primary outcomes- HgbA1C, FBS, BMI, weight F/u ranged between 8 weeks-2 years. All had follow-up at 6 months. Interventions: Mixed RCTs and quasi-experimental studies regarding DSME strategies that included either collaborative goal setting, individual or group education, telehealth communication or culturally tailored information.	5 articles using behavioral theory improved glycemic control compared to control. 4 of 6 articles culturally tailored showed significant in group differences for BMI, weight or HgbA1C. 5 articles including collaborative goal setting and individual motivation showed significant improvements in HgbA1C. Mixed intervention effects on biological outcomes. Only few demonstrated group differences in A1C, lipids, BMI or BP.	Both in person DSME and telehealth interventions have potential to be effective for patients with T2DM in rural areas. Interventions including motivation support may be more likely to improve metabolic control. Intervention dose linked to better outcomes and higher attendance.	None	Level III/A
Pal et al. (2013)	SR/Meta-analysis	16 studies. N=3578 adults with Type 2 DM. Mean age range 46-67 years, mean diagnosis of DM 6-13 years. Internet-based	Primary outcomes- glycemic control, HRQOL Secondary- social support, knowledge, behaviors, biological markers (BMI, lipid control) Interventions were RCTs focused on computer based self-management applications that respond to participant input and provide tailored content (i.e. reinforcement, motivation, goal-setting, problem solving, etc.) Compared to usual care, non-computer based interventions, paper education, delayed start or face-to-face education. Participants given access to intervention for 1-12 months	No SD in HRQOL. Small SD in glycemic control MD -0.2% (95% CI: -0.4 to -0.1; 2637 participants, 11 trials). Participants with baseline HgbA1C >7% difference between groups increased -0.14% to 0.6% (P=0.010). 4 of 4 studies showed positive effects on knowledge. 2 of 2 studies showed positive effects on self-efficacy. Significant improvement in dietary change scores SMD -0.29 (95% CI: -0.43 to -0.15; 89 participants, 3 trials.). No SD social support, lipid control, BMI.	Small benefit effect on blood glucose control; large effect in mobile subgroup. Patients with HgbA1C >7% may benefit more than patients with better baseline control. Interventions are poorly understood. Need further research to make definitive conclusions. Overall limited evidence supporting use.	None	Level I/A

APPENDIX D:
STAGES OF CHANGE QUESTIONNAIRE

Please circle the statement that relates to you the most:

- A. I am not aware that I am at risk for or have Chronic Kidney Disease.
- B. I am aware that I am at risk for or have Chronic Kidney Disease but have not made any changes in my diet, activity or other behaviors in order to reduce my risk and/or do not currently have plans to do so.
- C. I am aware that I am at risk for or have Chronic Kidney Disease but I am not sure what I need to do in order to reduce my risk or need help to make changes. I have been thinking about making a change in the next six months.
- D. I am aware that I am at risk for or have Chronic Kidney Disease and plan to make changes in the next month or sooner.
- E. I am aware that I am at risk for or have Chronic Kidney Disease and have made changes in my diet, activity or other behaviors in the last six months.
- F. I am aware that I am at risk for or have Chronic Kidney Disease and am confident in my ability to engage in activities to reduce my risk.

Scoring:

A & B: Pre-contemplation

C: Contemplation

D: Preparation

E: Action

F: Maintenance

Reference

Prochaska, J.O. & Clemente, C.C. (1983) Stages and processes of self-change of smoking: Toward an integrative model of change. *Journal of consulting and clinical psychology*, 51(3), 390-395.

APPENDIX E:
CKD COMMUNICATION CHECKLIST

CKD Communication Checklist

Stage of Change	Suggested Communication Points
<p><i>Pre-contemplation</i></p> <p>Goals at this stage: Increase awareness of individual risk and need for change. The patient does not see or is unaware of the need to change. ^{1,4}</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Discuss individual risk for CKD^{2,3,4} <ul style="list-style-type: none"> - Uncontrolled high BP and/or diabetes - Discuss individual kidney function <input type="checkbox"/> Discuss what CKD is and how this can affect the patient in the long-term. Patients can develop high blood pressure, anemia, weak bones, poor nutritional health and nerve damage. Increase risk for cardiovascular complications ^{4,5} <input type="checkbox"/> Discuss what the patient can do to reduce their risk of developing or progressing CKD (i.e. exercise, limit sodium intake, limit use of non-steroidal anti-inflammatory medication, manage BP and/or blood sugar, etc.) ^{4,5,6,7} <input type="checkbox"/> Ask if they have tried anything in the past to reduce their risk for progressing or developing CKD^{7,8}
<p><i>Contemplation</i></p> <p>Goals at this stage: Use motivational and encouraging statements to increase confidence in the patient's ability to change. The patient is still not sure if he or she can be successful. ^{9,12,13,14}</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Discuss benefits of making lifestyle changes such as exercising or eating healthy and how this may affect their risk related to CKD ^{1,4} <input type="checkbox"/> Goal setting ^{4,6,7,9,10} <ul style="list-style-type: none"> - Discuss what the patient can do to reduce their risk of developing or progressing CKD (i.e. exercise, manage BP and/or blood sugar, etc.)^{4,5} - What would you like to accomplish in the future in order to reduce your risk for CKD?^{4,6,7,9,10} <input type="checkbox"/> Barrier identification/Problem solving^{4,6,7,8,10,11} <ul style="list-style-type: none"> - On scale 1-10 how confident are you in achieving your goals related to CKD?^{4,6,7} - What do you feel is hindering you from achieving your goals?^{4,6,7} - What have you tried in the past?^{7,8} - Help patient see they are capable of achieving their goals^{8,9,10,11,12,13,14}

<p><i>Preparation</i></p> <p>Goals at this stage: Use positive reinforcement and recognize the patient's desire to change. Make encouraging statements, the patient is ready to change.^{1,9,12,13,14,15,16}</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Praise patient for taking the step to attempt change^{9,12,13,14} <input type="checkbox"/> Goal setting^{4,6,7,9,10} <ul style="list-style-type: none"> - What would you like to accomplish related to your risk of CKD between now and our next visit?^{4,6,7,9,10} - Set specific, measureable and achievable goals⁴ - On scale 1-10 how important is it to you to achieve this goal?^{6,7} <input type="checkbox"/> Barrier identification/Problem solving^{4,6,7,8,10,11} <ul style="list-style-type: none"> - What do you feel is hindering you from achieving your goal?^{4,6,7} - How confident are you in achieving this goal on scale 1-10?^{4,6,7} - Discuss and develop strategies to overcome barriers^{6,7,8,10,11} <input type="checkbox"/> Encourage support from family and friends^{4,17} <input type="checkbox"/> Acknowledge your support of the patient's goal^{1,9,12,13,14,15,16} <input type="checkbox"/> Ask the patient to repeat goals to ensure understanding^{4,6,7}
<p><i>Action</i></p> <p>Goals at this stage: Reevaluate goal and encourage continued change. The patient has made the step to make a change. He or she needs continued support and motivation.^{1,4,9,12,13,14,15,16}</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Praise patient for making a change^{9,12,13,14} <input type="checkbox"/> Goal setting- Re-evaluate goal^{4,6,7,9,10} <ul style="list-style-type: none"> - Do you feel you were able to accomplish your goal?^{6,7,8,10,11} - Were there any barriers hindering you from achieving your goal?^{4,6,7} - How did you overcome the obstacles?^{7,8} <input type="checkbox"/> Discuss how making the change may have impacted individual risk related to CKD^{2,3,4} <ul style="list-style-type: none"> - Discuss kidney function - Discuss BP and/or blood sugar control
<p><i>Maintenance</i></p> <p>Goals at this stage: Patient continues to make change. Make encouraging statements to instill confidence to continue change. Patient needs support to prevent relapse.^{1,4,9,12,13,14,15,16}</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Praise patient for continued change^{9,12,13,14} <input type="checkbox"/> Goal setting^{4,6,7,9,10} <ul style="list-style-type: none"> - Evaluate previous goals and celebrate success^{4,6,7,9,12,13,14} - Develop new specific, realistic and measureable goals^{4,6,7,9,10} - On scale 1-10 how important is it to you to

achieve this goal?^{6,7}

- Barrier identification^{4,6,7,8,10,11}
 - How confident are you on scale 1-10 to continue change?^{4,6,7,8,10,11}
 - Help patient see they are positively benefiting from change^{15,16}
 - How do you think making the change has affected your individual risk for CKD?^{15,16}
 - Acknowledge your continued support and identify further resources patient may need^{1,2,3,4,9,12,13,14,15,16}
- Re-emphasize benefits of change relating to overall health and individual risk related to CKD^{2,3,4,15,16}
 - Discuss kidney function
 - Discuss BP and/or blood sugar control
 - Discuss pertinent lab work- recognize any positive changes

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APPENDIX F:
HUMAN SUBJECTS DETERMINATION



Human Subjects
Protection Program

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Date:	October 16, 2015
Principal Investigator:	Roseanne Prieto
Protocol Number:	1510158052
Protocol Title:	Preventing Progression to End Stage Renal Disease: A Systematic Review of Patient-Provider Communication in the Primary Care Setting
Determination:	Human Subjects Review not Required

The project listed above does not require oversight by the University of Arizona because the project does not meet the definition of 'research' and/or 'human subject'.

- **Not Research as defined by 45 CFR 46.102(d):** As presented, the activities described above do not meet the definition of research as cited in the regulations issued by the U.S. Department of Health and Human Services which state that "research means a systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge".
- **Not Human Subjects Research as defined by 45 CFR 46.102(f):** As presented, the activities described above do not meet the definition of research involving human subjects as cited in the regulations issued by the U.S. Department of Health and Human Services which state that "human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention *or* interaction with the individual, or identifiable private information".

Note: Modifications to projects not requiring human subjects review that change the nature of the project should be submitted to the Human Subjects Protection Program (HSPP) for a new determination (e.g. addition of research with children, specimen collection, participant observation, prospective collection of data when the study was previously retrospective in nature, and broadening the scope or nature of the research question). Please contact the HSPP to consult on whether the proposed changes need further review.

The University of Arizona maintains a Federalwide Assurance with the Office for Human Research Protections (FWA #00004218).

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