Improving Chronic Kidney Disease Care With Group Visits

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IMPROVING CHRONIC KIDNEY DISEASE CARE WITH GROUP VISITS

by

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ABSTRACT

First year death rates remain unacceptable high for the end-stage renal disease (ESRD) population. New effective methods are vital to improve first year morbidity and mortality outcomes for the population transitioning from Stage 4 chronic kidney disease (CKD) to ESRD)/Stage 5 CKD. Based on current methods, evidence-based recommendations made by nephrology providers are frequently not heeded by patients in Stage 4 CKD. Low levels of patient knowledge, self-efficacy, and a poor ability to self-manage CKD negatively influence a patient's ability to follow provider recommendations. The group visit (GV) intervention has demonstrated improvements in disease-related outcomes through increased levels of patient knowledge, self-efficacy, and disease self-management for other chronic diseasses such as diabetes and congestive heart failure (CHF). No data are available for the use of GVs in CKD

The purpose of the study was to develop and test a nurse practitioner-facilitated chronic CKD GV model versus usual nephrology care for Stage 4 CKD patients (knowledge, self-efficacy/self-management, physiological data, and satisfaction). As classified by the National Kidney Foundation's (NKF) staging system, Stage 4 CKD is considered severe kidney disease, with a decrease in the functional capacity of the kidney as determined by a glomerular filtration rate (GFR) of 15-30 ml/min. It is common for patients with Stage 4 CKD to progress to Stage 5 CKD/end-stage renal disease (ESRD), requiring dialysis or transplantation to survive.

Preliminary instrumentation and feasibility studies were conducted prior to a pilot study of a CKD GV model. The development and validation of the *Stage 4 CKD Knowledge Instrument* was completed with 59 Stage 4 patients. Findings supported reliability (Kuder-Richardson-20 [KR] = .89) and content validity (I-CVI = .97, S-CVI= 1.0) Feasibility of the CKD GV model was assessed with a single group, pretest-posttest design using a convenience

sample of eight Stage 4 patients. Results demonstrated an improvement in knowledge of CKD from a median of 69% to 86% (p =.012). No improvements were noted in self-efficacy scores (p = .230). GV satisfaction ranged from very good to excellent. Feasibility was supported by a high retention rate (100%). No barriers to participant recruitment or GV implementation were encountered.

The pilot study used a two-group, repeated measures experimental design, with a sample of 30 Stage 4 CKD patients from two office locations of an outpatient nephrology practice. Patients were randomized to the GV intervention or to usual nephrology care. CKD-knowledge, self-efficacy, and self-management scores were collected at baseline, six months, and nine months. Physiological data were measured at baseline, six months, and nine months. GV satisfaction was obtained after the completion of GVs (six months). Nephrology practice satisfaction was obtained from by both groups at nine months. MANOVA for repeated measures was calculated for data collected at the three time points.

Twenty-six of 30 patients completed the study, with four patients ineligible to complete the study due to progression to ESRD and dialysis initiation. GV attendance was 92%. CKD knowledge was statistically improved for both groups ($F(1.498, 34.446) = 6.363$, $P = .008$). While not statistically significant, a favorable upward trend in the mean scores for the subscales of self-management (communication, partnership in care, and self-care) was demonstrated in the GV patients, with a lack of improvement found in the usual care group for these subscales. Self-efficacy scores revealed a non-significant improvement in mean scores for the GV patients during the GVs, not seen with usual care patients. GV satisfaction was again high with the vast majority of patients requesting use of GVs in their future nephrology care.

Current methods of intervention in the Stage 4 CKD population have made little impact on reducing first-year ESRD mortality and morbidity rates. Opportunities to intervene in the poor outcomes begin in the predialysis care of Stage 4 patients. Based on the documented success of multidisciplinary approaches in predialysis care, of GVs in other chronic diseases, and of chronic illness care based on the CCM, a high probability for success exists with the application of GVs in CKD. Although limited by a small sample size, promising improvements in the subscales of disease self-management, self-efficacy, CKD knowledge, and high satisfaction with the GV model for GV participants were revealed in this study. Further research is warranted for the CKD GV model on a larger randomized sample in other locations. Much needed data would be provided on which to base decisions for use of the CKD GV intervention in the predialysis care of Stage 4 patients.

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CHAPTER ONE: GROUP VISITS IN THE MANAGEMENT OF CHRONIC KIDNEY DISEASE: AN OVERVIEW

Introduction

Chronic disease has replaced acute illness and infection as the leading cause of death in industrialized countries, with 7 out of 10 deaths in the U.S. attributable to chronic diseases (Kung, Hoyert, Xu, & Murphey, 2008). Kidney disease was the 9th leading cause of death in 2009. Current estimates reveal that greater than 1 out of 10 persons aged 20 years or older (or greater than 20 million adults) have chronic kidney disease (CKD) (Plantinga, Crews, Coresh, Miller, Saran, et al., 2010). Left untreated or inadequately treated, CKD often progresses to end-stage renal disease (ESRD)/Stage 5 CKD, requiring dialysis or transplantation to survive. Despite provider recommendations for medications and lifestyle adjustments that delay the progression of CKD and improve CKD-related outcomes, alarming rates of morbidity and mortality prevail as patients with Stage 4 CKD progress to ESRD/Stage 5 CKD [National Kidney Foundation (NKF), 2002; Unites States Renal Data System (USRDS), 2011].

Patients' lack of sufficient knowledge, low levels of self-efficacy, and a poor ability to self-manage their CKD frequently interfere with the improved outcomes associated with provider recommendations. Due to the multiple and ongoing needs of patients with CKD, it is not feasible that a busy practitioner can deliver all of the care that is needed for optimal outcomes in the current health care setting. New effective interventions are needed that incorporate strategies which engage CKD Stage 4 patients as active participants in their chronic disease management.

Multidisciplinary interventions can provide the additional care necessary to bolster patient levels of disease-specific knowledge, self-efficacy, and CKD self-management, enabling

them to carry out the recommendations that they receive during office visits (Beaulieu & Levin, 2009; Bennett, 2007; Collister, Rigatto, Hildebrand, Mulchey, Plamondon, Sood, et al., 2010; Dixon, Borden, Kaneko, & Schoolwerth, 2011; Levin, Lewis, Mortiboy, Faber, Hare, Porter, et al. 1997; Levin & Stevens, 2005; Neyhart, McCoy, Rodegast, Gilet, Roberts, Downes, 2010; & Spry, 2008). Group medical visits (GVs) are one type of multidisciplinary intervention which has been suggested to improve chronic illness care to patients with Stage 4 CKD (Young, Chan, Yevzlin, & Becker, 2011).

Supported by the Institute for Healthcare Improvement (IHI) and Improving Chronic Illness Care, a national program of the Robert Woods Johnson Foundation (RWJF), the GV strategy provides chronic illness patients and their family members opportunities to assume their own care under the guidance and direction of their provider [RWJF, 2012; IHI, 2010]. The use of group medical visits in a variety of other chronic diseases such as diabetes, cardiovascular disease, COPD, and hypertension has demonstrated extensive improvements in many aspects of chronic illness care (Table 1).

Among the improvements, increased levels of disease-specific knowledge (Trento, Passera, Tomalino, Bajardi, Pomero, Allione, et al., 2001**;** Trento, Passera, Bajardi, Tomalino, Grassi, Borgo, et al., 2002; Wagner, Austin, Davis, Hindmarsh, Schaefer, & Bonomi, 2001) and self-efficacy/disease self-management (Clancy, Brown, Magruder, & Huang, 2003; Ersek, Turner, McCurry, Gibbons, & Kraybill, 2003; Kirsh, Watts, Pascuzzi, O'Day, Davidson, Strauss, et al., 2007; Scott, Conner, Venohr, Gade, McKenzie, Kramer, et al., 2004; Trento, et al., 2001; Trento, et al., 2002) have resulted from patient enrollment in GVs. Increases in knowledge and self-efficacy/disease self-management led to sustained health behavior change and improved patient outcomes for patients enrolled in the GVs (Trento, et al., 2001; Trento, et

al., 2002, Wagner, et al., 2001; Bartley & Haney, 2010; Beck, Scott, Williams, Robertson, Jackson, Gade, et al., 1997; Blumenfeld & Tischio, 2003; Clancy, Huang, Okonofua, Yeager, & Magruder, 2007; Coleman, Eilertsen, Kramer, Magid, Beck, & Conner, 2001; De Vries, Darling-Fisher, Thomas, & Belanger-Shugart, 2008; Loney-Hutchinson, Provilus, Jean-Louis, Zizi, Ogedegbe, & McFarlane, 2009; Maizels, Saenz, & Wirjo, 2003). Improvements in patients' chronic disease outcomes (physiological parameters and reduction in comorbidity status) were observed in multiple studies (Clancy, et al., 2003; DeVries, et al., 2008; Ersek, et al., 2003; Jaber, Braksmajer, & Trilling, 2006; Kirsh, et al., 2007; Maizels, et al., 2003; Trento, et al., 2001; Trento, et al., 2002). Studies which assessed patient satisfaction with GVs also found positive responses (Beck, et al., 1997; Blumenfeld & Tischio, 2003; Clancy, Brown, Magruder, & Huaung, 2003; Coleman, Grothaus, Sandhu, & Wagner, 1999; DeVries, et al., 2008; Jaber, et al., 2006; Miller, Zantop, Hammer, Faust, & Grumbach, 2004; Scott, Conner, Venohr, Gade, McKenzie, Kramer, et al., 2004; Thacker, Maxwell, Saporito, & Bronson, 2005; and Wagner, et al., 2001).

GVs are planned medical appointments in a group setting of usually 10-20 participants. The visits include an educational component and elements of an individual patient visit (vital signs, history taking, physical exam). Thus, patients have both a group and a one-on-one consultaion experience at each visit. Sometimes referred to as shared medical appointments, group visits differ from other types of group interventions which are generally led by peers and do not include the one-on-one consultation with the physician or nurse practitioner (NP). Specialists in a disease-related topic, such as a dietician or physical therapist, often lead the interactive discussion within the group. Group participants usually have a common chronic disease.

The CKD GV was developed by this investigator based on examples of various GVs in other chronic diseases.The CKD GV included a combination of the regularly scheduled office visit with the patient's nephrologist or NP and an interactive group discussion of CKD-related topics in a group setting. The GV was set up in two parts. The first part of the GV was the one-on-one consultation with the nephrologist. The second part was the interactive group discussion on a focused topic led by a nephrologist, NP, or other specialist in the CKD-related topic.

Study Purpose and Aims

The primary aim of the pilot study was to assess the efficacy of a nurse practitioner-facilitated CKD GV model versus usual nephrology care. A secondary aim was to obtain effect size estimates for a larger study. The specific hypotheses were:

As compared to Stage 4 CKD patients who receive routine nephrology care, those who participate in the CKD GV model will:

1) Demonstrate greater levels of CKD knowledge
2) Show greater levels of self-efficacy and self-management of CKD
3) Improve achievement of target physiological endpoints: blood pressure control, lipid levels, hemoglobin A1c (if diabetic), and normovolemia
4) Show greater slowing of renal disease progression as determined by the eGFR/creatinine
5) Describe higher levels of satisfaction with nephrology care

Theoretical Framework

The theoretical framework for nurse-practitioner-facilitated CKD GVs was based on Social Cognitive Theory (SCT) (Bandura, 1986) and the Chronic Care Model (Chronic Care Model, 2006).

Social Cognitive Theory

According to SCT, a person's behavior is uniquely determined by the interaction of three factors: (1) personal factors, (2) behavior, and (3) the environment (Figure 1). Response consequences of a behavior are used to form expectations of the behavioral outcomes. An individual's ability to form these expectations gives them the capability to predict the outcomes of a particular behavior before engaging in that behavior. While the SCT asserts that the interaction of personal factors, behavior, and the environment determines behavior, the theory also recognizes that the degree of each factor's influence on behavior is variable. This variation occurs as a result of the individual contemplating the behavior, the particular behavior in question, and the specific situation in which the behavior occurs (Bandura, 1989).

Six core determinants form the foundation for effective health promotion and disease prevention (Bandura, 2004). The determinants include: 1) knowledge of health risks and benefits of different health practices, 2) perceived self-efficacy or the belief that one can exercise control over one's health habits, 3) outcome expectations regarding the expected costs and benefits of adopting a behavior, 4) health goals, 5) perceived facilitators to the behavior, and 6) social and structural impediments to the change that is sought.

While each of the determinants is an important piece of sustained behavior change, the focus for the scope of the pilot study was on the first two determinants: knowledge of health risks and benefits of different health practices and perceived self-efficacy. Knowledge of health risks and benefits, the first core determinant, creates a precondition for behavior change (Bandura, 2004). A person will not contemplate a change in enjoyable habits if he/she does not know how it is detrimental to their health. While a great deal of health education is directed at

increasing patient's knowledge regarding a particular disease state, little change is achieved by increasing knowledge alone.

In addition to knowledge, beliefs of self-efficacy are necessary to adopt new lifestyles and maintain them (Bandura, 2004). As the second core determinant, self-efficacy is the foundation of human motivation and change. A patient's expectations of personal efficacy are derived from four principle sources of information (Bandura, 1977). The sources are: 1) Performance accomplishments (past experiences of success or failure), 2) vicarious experience (seeing others perform a task successfully), 3) verbal persuasion by others deemed knowledgeable about the behavior (giving instructions, suggestions, or advice), and 4) physiological feedback (anxiety, depression, pain). Performance accomplishment is the most powerful source, as it is based on direct information. Interventions delivered in a group setting provide an opportunity to build self-efficacy through all four sources (Lorig, Sobel, Ritter, Laurent, & Hobbs, 2001).

Self-efficacy beliefs are specific for a certain behavior, as opposed to a generalized predisposition or attitude such as optimism or high self-esteem (Clark & Dodge, 1999; Maibach & Murphy, 1995). Persons with high levels of self-efficacy are also more likely to sustain their healthy behaviors, as they view obstacles as challenges to overcome as opposed to roadblocks (Maibach & Murphy, 1995). The measurement of self-efficacy should ideally be assessed at the optimal level of specificity that corresponds to a specific task or behavior (Bandura, 1997). While different groups of people with a particular chronic disease basically share the same self-care tasks, the individual perception of the tasks can differ greatly due to stage of the disease, culture, and age group (van der Bijl & Shortridge-Baggett, 2001).

Chronic Care Model

The Chronic Care Model (CCM) was developed more than 15 years ago by the staff at MacColl Center for Healthcare Innovation at Group Health Research Institute. The CCM is a framework for chronic illness care that has been rigorously evaluated and revised through funding by the Robert Woods Johnson Foundation (RWJF) and the national Improving Chronic Illness Care program (Group Health Research Institute, 2006). System changes were constructed as a synthesis of evidence-based system changes which promote quality chronic disease management. The CCM has been utilized and studied in primary care in countries such as the United Kingdom, Australia, Canada, and the U.S.

The CCM summarizes the basic elements for improving chronic illness care in health systems at the community, organization, practice, and patient levels. The six elements include: organization of health care, community resources, delivery system design, decision support, clinical information systems, and self-management support (Chronic Care Model, 2006) (Figure 2; see also Chapter 2).

The CCM calls for health care that is proactive, in which the goal is to keep a person as healthy as possible (Chronic Care Model, 2006). When the CCM framework is used, systematic assessments of patients are required in addition to regularly scheduled follow-up visits, attention to treatment guidelines, education for patients and families, psychosocial support, and self-management skills (Wagner, Austin, & Von Korff, 1996).

Evaluation of care based on the CCM demonstrated improvements in both processes of care and patient outcomes in chronic diseases such as congestive heart failure, diabetes, asthma, and depression. The extensive success of the CCM use in other chronic diseases suggests that the same would be true in CKD. Application of the CCM in CKD has been supported by the

National Kidney Disease Education Program (NKDEP), established in 2000 by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) (NKDEP 2009).

A meta-analysis of interventions to improve care for chronic illnesses found interventions containing at least one of six CCM elements improve clinical outcomes and processes of care (Tsai, Morton, Mangione, & Keeler, 2005). The CKD GV as a delivery system redesign is suggestive of similar improvements in care and patient outcomes in the outpatient nephrology practice. The CKD GV can potentially integrate changes in all 6 areas of the model (Figure 3). Consistent with the CCM, GVs promote patient-centered, multidisciplinary, evidence-based chronic illness care (Wagner, Bennett, Austin, Greene, Schaefer, & Vonkorff, 2005).

SCT, CCM, and GVs

A triadic relationship exists between SCT, the CCM, and GVs. Use of SCT in the application of the CCM for chronic illness care provides a backdrop for improvement in Stage 4 CKD patient outcomes through the GV intervention. Knowledge, self-efficacy, and disease self-management are central to SCT, CCM, and GVs in the context of chronic illness. According to SCT and the CCM, knowledge is an integral component of patient self-management. Healthcare interventions which use SCT as a framework have demonstrated improvement in self-management behaviors in persons with chronic disease (Celentano, Dilorio, Hartwell, Kelly, Magana, Maibach, et al., 2001; Clark & Dodge, 1999; DeBusk, Miller, Superko, Dennis, Thomas, Lew, et al., 1994; Gifford & Sengupta 1999; Hiltunen, Winder, Rait, Buselli, Carroll, & Rankin, 2005; Strathdee, Mausback, Lozado, Staines-Orozco, Semple, Abramovitz, et al., 2009). A meta-analysis of successful self-management interventions found that multiple studies supported self-efficacy as the theoretical framework (Marks, Allegrante, & Lorig, 2005a, 2005b).

Combination of the SCT and the CCM provide strong theoretical support for a randomized study of Stage 4 CKD GVs.

Preliminary Studies

Two preliminary studies were necessary prior to the pilot study: 1) an instrumentation study to develop and validate a Stage 4-specific CKD knowledge tool and 2) a feasibility study of GV in private nephrology practice. While several CKD knowledge tools were found in the literature that evaluate general CKD or ESRD knowledge, no Stage 4-specific tool was found. Hence, a 47-item instrument was developed and tested with 65 Stage 4 patients. Reliability (KR-20 = .89) and validity of this new instrument was supported. Details of development and psychometric testing of the Stage 4 CKD Knowledge Instrument are found in Chapter 3.

The second study gathered preliminary data regarding (a) the likelihood of success of a larger, randomized study and (b) how to to streamline the CKD GV model prior to its use in the pilot study. Using a single group, pre-test post-test design, data were collected at baseline (pre-intervention) and at five months (post- intervention). CKD knowledge, self-efficacy, disease self-management, physiological data, and satisfaction were measured. Knowledge of CKD improved after completion of the GVs from a median of 69% to 86% (related sample Wilcoxon signed rank, $p = .012$). Satisfaction surveys completed by participants post-intervention indicated high levels of satisfaction with the GV model, with all paticipants indicating a desire for continuation of CKD GVs in their future nephrology care. Recruitment, retention, and intervention delivery strategies appeared feasible for an office setting. Feasibility study details are found in Chapter 4.

Improving Chronic Kidney Disease Care with Group Visits: A Pilot Study

A two-group repeated measures design was proposed for the pilot study, with 30 Stage 4 CKD patients from two office locations of a single nephrology practice (15 patients per site). Patients were randomized to the CKD GV intervention or to usual nephrology care. Patients randomized to the CKD GV intervention met for six interactive CKD educational discussions, in conjunction with their usual 3-month physician office visits. The patients in the usual care group continued the 3-month office visits with their physician, with an option for the standard CKD education offered locally by an outside vender. CKD knowledge, self-efficacy/self-management, and physiological measurements were measured at baseline, six months, and nine months. GV satisfaction was measured at six months and nephrology practice satisfaction was measured at nine months. Details of the study are found in Chapter 5.

Tables and Figures

Table 1: Improvements Demonstrated with Use of GVs in Chronic Disease

Author(s)	Date of Publication	Chronic Disease	Type of Study/Article	Findings
Beck, et al.	1997	Elderly patients/varied	RCT, 321 subjects in HMO	3, 4, 6, 7, 10
Blumenfeld & Tischio	2003	Headache	Prospective pilot study, 497 subjects	4, 5, 6, 7
Clancy, Brown, Magruder, & Huaug	2003	Diabetes	RCT, 120 subjects	1, 6, 8
Clancy, Huaug, Okonofua, Yeager, & Magruder	2007	Diabetes	RCT, 186 subjects	4
Coleman, et al.	2001	Elderly patients/varied	RCT, 295 adults in HMO	4, 10
Coleman, Grothaus, Sandhu, & Wagner	1999	Frail, older adults	RCT, 169 subjects in HMO	1, 6
De Vries, Darling-Fisher, Thomas, & Belanger-Shugart	2008	COPD	Retrospective chart audit, pilot study, 6 subjects	4, 5, 6
Ersek	2003	Chronic pain	RCT, 6 mos, 45 subjects	1, 4, 5

Author(s)	Date of Publication	Chronic Disease	Type of Study/Article	Findings
Jaber,, Braksmajer, & Trilling	2006	Variety	Literature review of GV research from 1974-2004	3, 6, 7, 10
Kawasaki, Muntner, Hyre, Hampton, & DeSalvo	2007	Hypertension	Cross-sectional survey, 296 subjects	N/A
Kirsh, et.al.	2007	Diabetes/ High Cardiovascular Risk	Quasi-experimental with concurrent, nonrandomized controls	1, 4, 9
Maizels, Saenz, & Wirjo	2003	Headache	Prospective, open-label, observational study, 264 subjects	4, 9, 10
Miller, Zantop, Hammer, Faust, & Grumbach	2004	Low-income women with chronic disease	Mixed method, pre/post without control, 28 subjects	6, 8, 10
Scott, et al.	2004	Chronically ill older HMO members	2-yr RCT, 294 subjects	1, 5, 6, 10
Thacker, Maxwell, Saporito, & Bronson	2005	Chronically ill mid-life women	Retrospective, descriptive	6, 7, 9
Trento, et al.	2001	Non-insulin type 2 diabetics	2-yr RCT, 112 subjects	1, 2, 4, 5
Trento, et al.	2002	Non-insulin type 2 diabetics	4-yr RCT, 112 subjects	1, 2, 4, 5
Wagner, et al.	2001	Diabetes	2-yr RCT, 460 subjects	2, 3, 4, 5, 6

(RCT-Randomized controlled trial)

Findings Key for Table 1

1. Increased patient self-efficacy/self-management skills
2. Increased patient knowledge
3. Improved patient care
4. Improved outcomes per disease process (e.g., HgbA1c in diabetics, increased exercise tolerance in COPD)
5. Improved quality of life
6. Increased patient satisfaction
7. Increased provider satisfaction
8. Increased satisfaction and trust with provider
9. Increased in practice productivity/monetary benefits
10. Decreased ER visits

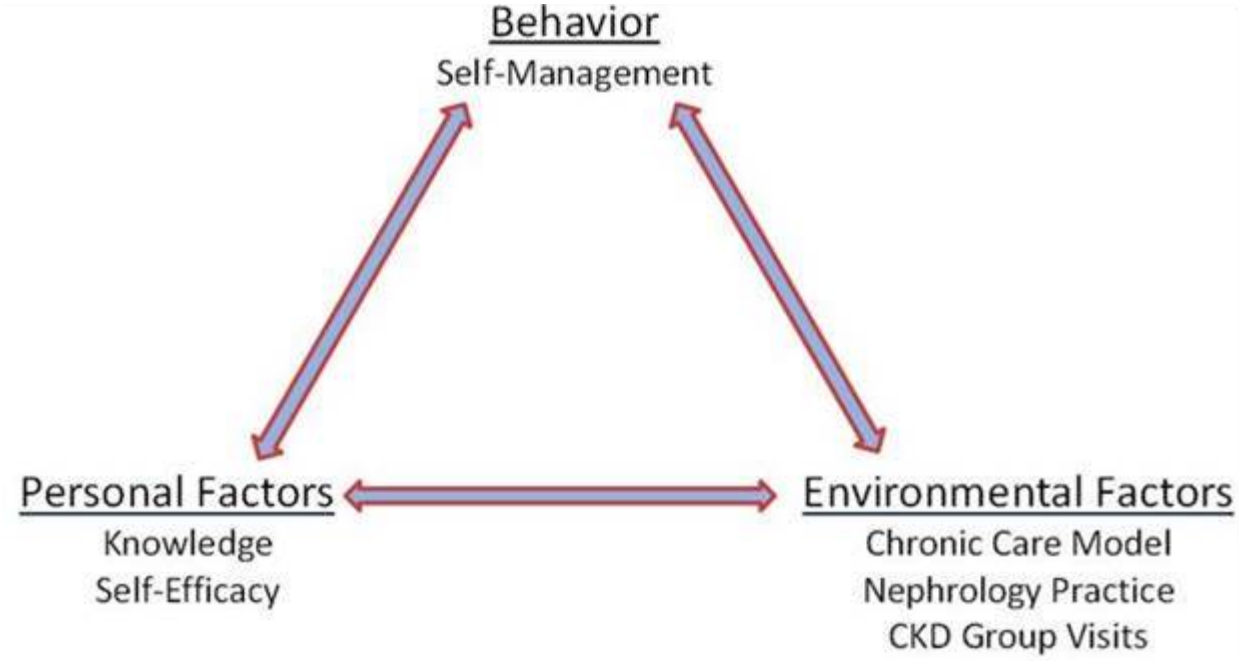
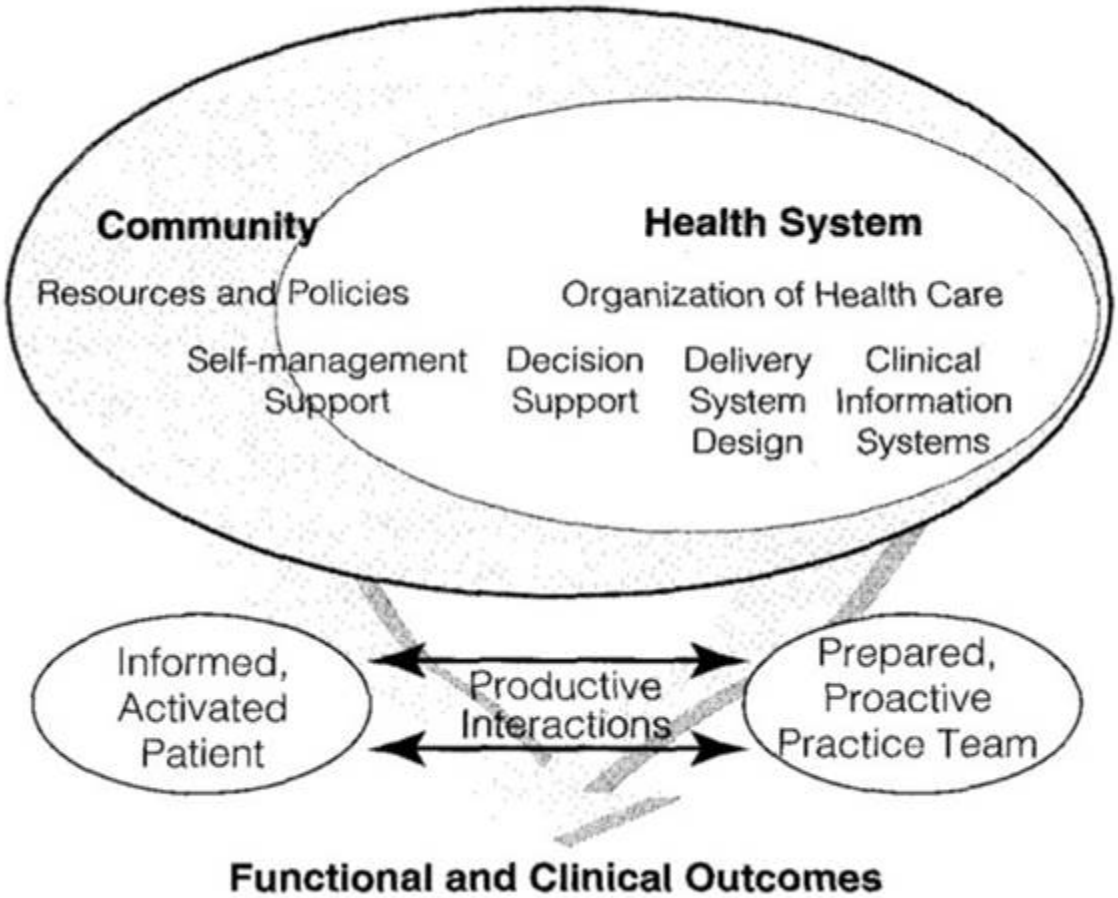


Figure 1: Social Cognitive Theory and the CKD Group Visit



Wagner, E.H. (1998). Chronic Disease Management: What will it take to improve care for chronic illness? Effective Clinical Practice,1; Reprinted with permission.

Figure 2: The Chronic Care Model

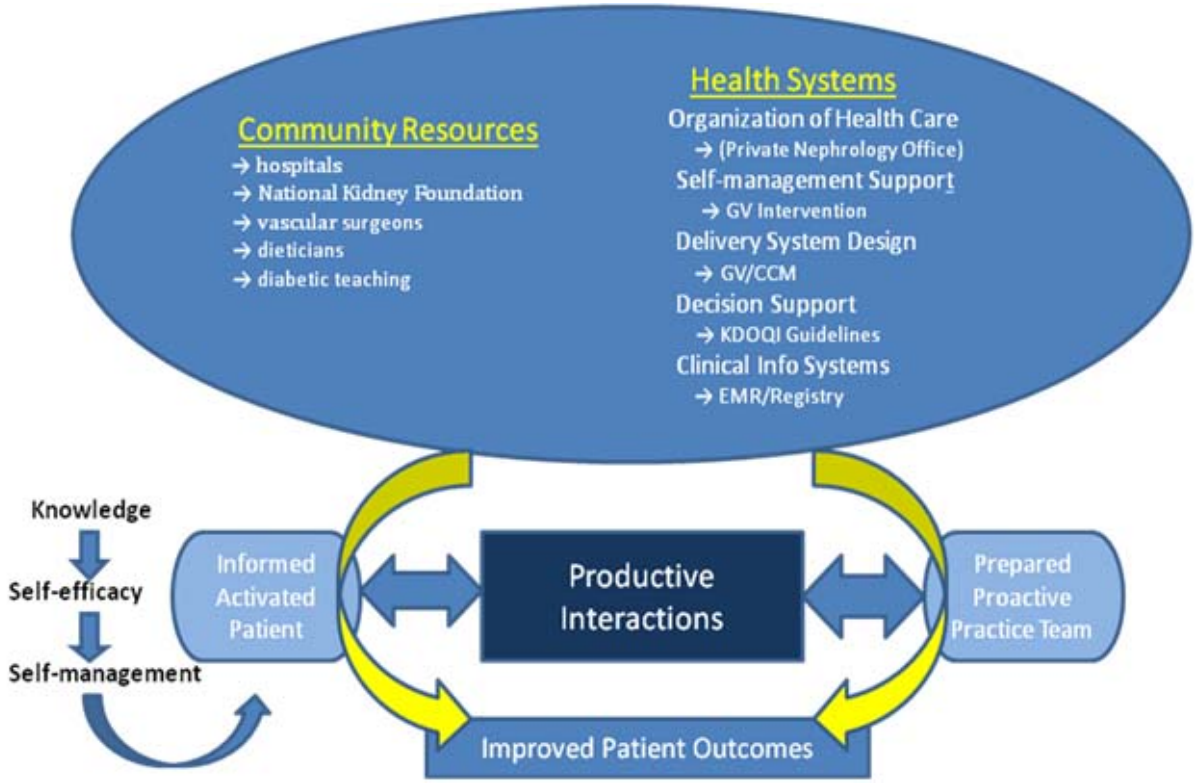


Figure 3: Group Visits and the Chronic Care Model

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CHAPTER TWO: THE CONCEPT OF CHRONIC ILLNESS CARE IN KIDNEY DISEASE: APPLICATION OF THE CHRONIC CARE MODEL

Abstract

Chronic illness care and chronic disease care are terms that are often used interchangeably in healthcare discussions regarding treatment of patients with a particular chronic illness, such as chronic kidney disease (CKD). Important differences in the terms remain unexplicated, leading to conceptual confusion and and a lack of comprehensive care. Given that one in ten persons age 20 or older have CKD and need comprehensive care, it is important to clarify the differences between these two terms.

A critical appraisal of the literature was conducted using Morse's method of exploring pragmatic utility of a concept to clarify the concept of chronic illness care and its preconditions, attributes, boundaries, and outcomes as it relates to nephrology providers and use of the Chronic Care Model. Relevant literature was selected using English articles from 2000-2011 in the following databases: CINAHL, Medline-Ebscohost, Cochrane Database of Systematic Reviews, and PsychInfo. Reference lists from selected articles were used to obtain the remaining literature.

Clarification of the concept of chronic illness care and its separateness from the concept of chronic disease care was accomplished in this concept analysis. The concept's two preconditions, five attributes, two boundaries, and five outcomes were identified as it relates to nephrology providers' provision of care to persons with CKD. The pragmatic utility of the concept of chronic illness care was advanced through clarification and provides a basis for nephrology care providers to apply the concept to their own practices of patient care.

Introduction

Kidney disease was the 9th leading cause of death in 2009 (Kochanek, Xu, Murphy, Minino, & Young, 2011). It is estimated that more than 10% of persons aged 20 years or older (or greater than 20 million adults) have chronic kidney disease (CKD) (Plantinga, Crews, Coresh, Miller, Saran, et al., 2010). Greater than 39% of persons aged 20 years or older with diagnosed diabetes have CKD and greater than 41% of persons with undiagnosed diabetes have CKD (Plantinga, et al., 2010). The costs to care for persons with chronic disease currently consume more than 75% of health spending, with an expected increase to 80% by 2020 (Kung, et al., 2008). A disproportionate amount of the spending is attributable to CKD. Representing 8.4% of the point prevalent population, CKD patients account for 17% of total expenditures (excluding ESRD patients on dialysis or with a kidney transplant) [United States Renal Data System (USRDS), 2011].

As a consequence of the rising numbers, costs, and the poor fit of current methods of care delivery, various models of chronic illness care and interventions have emerged. Disease management programs, patient self-management, electronic medical records (EMRs), evidence-based guidelines (EBGs), patient/medical staff disease-specific education, provider incentives, and, more recently, federally capitated spending in certain disease states, such as hemodialysis, are among suggested methods of improving chronic illness care. Busy health care providers are left confused as to which of the strategies are the most effective in improving the care of this growing population (Figure 1). Conflicting results exist in the literature as to the true impact of each approach.

Alternately, the Chronic Care Model (CCM) is a quality improvement framework developed by the staff at MacColl Center for Healthcare Innovation at Group Health Research

Institute (Group Health Research Institute, 2006) (Figure 2). With the support of the Robert Wood Johnson Foundation (RWJF) and the national Improving Chronic Illness Care program, the model was based on a Cochrane systematic review of chronic care interventions. The system changes were constructed as a synthesis of evidence-based system changes which promote quality chronic disease management. The CCM has been utilized and studied in primary care in countries such as the United Kingdom, Australia, Canada, and the U.S.

While academicians and health care providers have recognized the incongruence and need for new methods of chronic illness care, nephrology, as a specialty, remains only in the beginning stages of change. Due to the complex nature of CKD, the multiple associated morbidities, and the numerous educational and psychosocial needs of the patients, nephrology providers are unable to deliver the needed comprehensive care under the current system (Wellington, 2001). The National Kidney Disease Education Program (NKDEP), established in 2000 by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), has supported the application of the CCM in nephrology (NKDEP, 2009).

Purpose

The purpose of this inquiry is to examine and clarify the scientific concept of chronic illness care as it relates to nephrology providers' provision of care to persons with CKD. The ultimate aim is to establish the pragmatic utility of the concept when used in conjunction with the CCM and the CKD patient.

The concept of chronic illness care is considered to be a partially developed concept (Weaver & Morse, 2006). It is necessary to further delineate the concept to eliminate the

confusion of competing concepts such as chronic disease management and patient self-management.

Literature Search

Pragmatic utility is determined by critically appraising relevant literature in order to explore and develop the concept and the role it plays in inquiry (Morse, 2000). Relevant literature was selected using the following databases: CINAHL, Medline-Ebscohost, Cochrane Database of Systematic Reviews, and PsychInfo. Years included in the selection were 2000-2011. Key articles from the 1990's were also included. Only English language articles were used. Search terms included chronic illness care, chronic disease management, chronic kidney disease, self-management of chronic disease, and Chronic Care Model. Reference lists from relevant studies were examined to provide the remaining literature.

Definitions

As the terms of chronic disease and chronic illness are often used interchangeably, providers may not fully comprehend the inherent differences in each. To clarify the terms as they are intended in this review, the definitions follow (Table 1).

A chronic disease is a medical condition lasting 3 months or more, by the definition of the U.S. National Center for Health Statistics (Wu, 2000)**.** *Chronic disease refers to a diagnosis categorized in the biomedical system according to etiology, pathophysiology, signs, symptoms, and treatment.* It is thought to be an objective and definable process (Sperry, 2006).

Chronic illness refers to the irreversible presence, accumulation, or latency of disease states or impairments that involve the total human environment for supportive care and self-

care, maintenance of function, and prevention of further disability (Curtin & Lubkin, 1995). Sperry (2006) also describes chronic illness as the subjective experience of a chronic disease.

Chronic disease care includes the treatments prescribed to lessen or control symptoms of the condition. This form of care encompasses the prescriptions or recommendations to a patient, usually within a paternalistic form of care designed to treat the objective diagnosis. Relief of symptoms and normalization of deviant physiological measures are frequently the focus. For the most part, it is generally considered to be evidence-based care.

Chronic illness care includes chronic disease care as an integral component, but also includes systematic assessments, preventative interventions, education, psychosocial support, and follow-up (Wagner, Austin, & Von Korff, 1996; Wagner, Austin, Davis, Hindmarsh, Schaefer, & Bonomi, 2001). The lived experience of the chronic disease is treated in chronic illness care. Like chronic disease care, chornic illness care is evidence-based.The use of the CCM in health care delivery is consistent with chronic illness care.

Integrative Review of the Literature

Review of pertinent literature revealed numerous preconditions, attributes, boundaries, and outcomes of the concept of chronic illness care as it relates to nephrology providers (Table 2). Each will be discussed separately as it uniquely contributes to the development of the concept of chronic illness care.

Preconditions

Review of the literature revealed preconditions that must be present prior to chronic illness care. A provider appointment with the CKD patient is the first prerequisite that is necessary. The nephrology provider must perceive the value of comprehensive, high quality care

and be motivated to make changes in the current method of care delivery in order to deliver comprehensive, high quality care. Two-thirds of physicians report that their training is inadequate to coordinate care for or to educate patients with chronic conditions, with less than 36% of physicians satisfied with caring for patients with chronic disease (Partnership for Solutions, 2002). The nephrology specialty has recognized that poor outcomes for patients with CKD are reflective of the current method of care and the specialty is ready to make a change (Beaulieu & Levin, 2009; Chen, Scott, Mattern, Mohini, & Nissenson, 2006; Collister, Rigatto, Hildebrand, Mulchey, Plamondon, Sood, et al. 2010**;** Dixon, Borden, Kaneko, & Schoolwerth, 2011**;** Hopkins. Garg, Levin, Molzahn, Rigatto, Singer, et al., 2011; Neyhart, McCoy, Rodegast, Gilet, Roberts, & Downes, 2010**;** & Spry, 2008).

Attributes

Several elements of chronic illness care are necessary to achieve optimal outcomes for the CKD patient. These elements, or attributes, function in an interdependent fashion. The attributes of patient-centered care, multidisciplinary care, evidence-based care, promotion of patient self-management, and patient education can be combined in current nephrology practice when changes are made to the health care delivery system using the CCM.

Patient-centered Care

Patient-centered care has been identified in the Institute of Medicine (IOM) report *Crossing the Quality Chasm* as one of the six components of quality care (IOM, 2001). Patient-centered care focuses not only on the chronic disease process and the application of evidence-based medicine to treat the disease, but on the person as a whole. The patient's cultural, psychosocial, economic, and family support background all play significant roles in how the

evidence-based recommendation that the provider gives may or may not fit in their life situation. Stewart (2000) revealed that the average patient-centered score of doctors' delivery of care on a scale of 0 to 100 was 50.7 (SD 17.9, range 8-93).

Arguments persist amongst providers that evidence-based medicine (EBM) and patient-centered medicine are contradictory terms. Bensing (2000) reported that an analysis of the literature revealed that EBM and patient-centered medicine appear to belong to separate worlds. Provider communication is tantamount to bridge this gap between the two worlds, (Bensing, 2000; Lewin, Skea, Entwistle, Zwarenstein, & Dick, 2001; Michel & Moss, 2005; Stewart, Brown, Donner, McWhinney, Oates, et. al., 2000; Street, Makoul, Arora, & Epstein, 2009; and Thorne, Harris, Mahoney, Con, & McGuinness, 2004). An example of co-existence between patient-centered care and EBM is the nephrologists' discussion of patient prognosis prior to the initiation of dialysis (Michel & Moss, 2005). The prognosis conversation between the physician and the patient requires tailoring the communication according to the individual patient's preferences, based on their cultural, ethnic, or educational background.

A Cochrane review done to evaluate provider interventions which promote a patient-centered approach determined that not only was patient-centeredness increased in patient encounters with the interventions, but patient satisfaction with care improved as well (Lewin, et al, 2001). A patient-centered educational intervention was used in a randomized controlled trial by Manns, et al. (2005) to determine the impact of the intervention on CKD patients' plans to initiate dialysis with self-care dialysis (peritoneal or home hemodialysis). The proportion of patients selecting self-care dialysis at the end of the intervention was significantly more than those receiving standard care ($p = 0.015$). A predialysis psychoeducational intervention, also patient-centered, compared time to dialysis initiation in an intervention group to a usual care

group (Devins, Mendelssohn, Barre, & Binik, 2003). Time to dialysis initiation was significantly longer in the intervention group (median, 17.0 months) than in the usual care group (median, 14.2 months) ($p < 0.001$).

Another patient-centered intervention involving health care practice redesign as included in the CCM is that of the CKD group visit. Elements of a usual nephrology visit, including a physical examination, are components of the group visit, in addition to an interactive discussion of CKD-related topics. The use of group medical visits in a variety of other chronic diseases such as diabetes and heart failure has demonstrated an ability to increase levels of patient knowledge, self-efficacy, and chronic disease self-management, leading to sustained health-related behavior change and improved patient outcomes. Wagner (2005) supports the use of group visits as part of health care delivery system redesign in the CCM. The group medical visit (GV) has recently been suggested as a novel method of providing needed chronic illness care to Stage 4 CKD patients (Young. Chan, Yevzlin, & Becker, 2011).

Multidisciplinary Care

Due to the multiple and ongoing needs of patients with chronic disease, it is not feasible that a busy practitioner can deliver all of the care that is needed for optimal outcomes in the current health care setting. Multidisciplinary care, an additional attribute, is vital to achieve effective chronic illness care. Patient care teams, such as those found in multidisciplinary care, consist of diverse health care professionals who work together to deliver needed care. The clinical role possessed by each team member determines the delegation of care functions. Nephrologists, advanced practitioners, RN's, dieticians, social workers, transplant coordinators, and pharmacists combine their fields of expertise to accomplish the comprehensive care for the

CKD population that could not be attained by a single provider. Certain aspects of chronic care are frequently those that the physician does not have the skills or the time to deliver, such as behavioral change and dietary instruction.

Multidisciplinary care in CKD is supported in literature (Beaulieu & Levin, 2009; Bennett, 2007; Collister, et al., 2010; Dixon, Borden, Kaneko, & Schoolwerth, 2011; Levin, Lewis, Mortiboy, Faber, Hare, Porter, et al., 1997; Levin & Stevens, 2005; Neyhart, et al., 2010; & Spry, 2008). Supervised by physicians, chronic care is successfully administered by patient care teams via algorithms, protocols, and Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines in CKD and anemia clinics in many nephrology practices.

Improved patient outcomes in CKD have been noted in several recent studies using multidisciplinary care. Dixon, et al. (2011) compared outcomes of patients who received traditional nephrology care with those who received CKD care using a multidisciplinary care model. Results showed that, at the time of dialysis initiation, the patients enrolled in the multidisciplinary care model had significantly more fistulas in place than those in traditional care (60.7% vs. 21%, $p < 0.001$), more arterio-venous fistulas (AVFs) utilized for their first dialysis (40.4% vs. 12.3%, $p < 0.001$), higher hemoglobin levels (10.9g/dL vs. 10.0g/dL, $p < 0.003$), and higher albumin levels (3.7 vs. 3.6, $p = 0.04$).Those in the multidisciplinary group also were more likely to have dialysis initiated in an outpatient setting instead of at the hospital (62.9% vs. 36.6%, $p < 0.001$). The impact of multidisciplinary predialysis programs on patient outcomes was also examined in two Canadian settings (Levin, et al., 1997). In one setting, it was found that there were significantly fewer urgent dialysis starts for patients in the predialysis program (13% vs. 35%, $p < 0.05$), fewer days per hospital admission in the predialysis program (6.5 v. 13.4, $p < .005$), and less frequent hospitalization for symptoms of uremia for the predialysis group (3 vs.

11, $p < 0.005$). The second setting showed successful placement of a dialysis access prior to the first dialysis in 86.3% of the patients exposed to multidisciplinary care who chose peritoneal dialysis. For those choosing hemodialysis in the multidisciplinary group, AVFs were placed in 68% of the patients and grafts were placed in 32% of the patients, both prior to dialysis initiation.

Hemmelgarn, et al. (2007) determined that inclusion in a multidisciplinary care clinic for elderly patients over the age 66 years was associated with a 50% reduction in the risk for all-cause mortality as compared to those receiving usual nephrology care (HR .50; 95% CI 0.35 to 0.71). Another survival benefit was demonstrated in a two country study in which patients were evaluated at and after dialysis initiation when exposed to either multidisciplinary care or to usual nephrology care (Curtis, Ravani, Malberti, Kennett, Taylor, Djurdjev, et al., 2005). Cox proportional hazards analysis determined that inclusion in the multidisciplinary clinic vs. standard nephrology care was a statistically significant independent predictor of death, with multidisciplinary patients having a 50% reduction (HR = 2.17; 95% CI 1.11-4.28).

Evidenced-based Care

The third attribute of chronic illness care is evidence-based care. Evidence-based care is delivered to specific patient populations through the use of clinical practice guidelines (CPGs). The goal of these guidelines is to reduce disparities in practice and integrate best available research evidence into clinical decision-making (Maue, Segal, Kimberlin, & Lipowski, 2004). In spite of this goal, the general rate of clinician adherence to CPGs is frequently less than 55% (Desai, Garber, & Chertow, 2007; Goldman, 2006; Maue, Segal, Kimberlin, & Lipowski, 2004; McGlynn, Asch, Adams, Keesey, Hicks, DeCristofaro, et al., 2003; McKinlay, Link, Freund, Marceau, O'Donnell, Lutfey, 2007; & Rosen, 2006). Lack of CPG use in chronic illness care

contributes to the poor outcomes experienced by this population (Bodenheimer, Wagner, & Grumbach, 2002; Coleman, Mattke, Perrault, & Wagner, 2009; Wagner, et al., 1996; Wagner, et al., 2001).

Several studies support improvement in patient outcomes as a direct relationship of improvement in care processes in various chronic illnesses (Clancy, Cope, Magruder, Huang, & Wolfman, 2003; Clancy, Huang, Okonofua, Yeager, & Magruder, 2007; Solberg, Crain, Sperl-Hilton, Hroscikoski, Engebretson, & O'Conner, 2006; and Wagner, Grothaus, Sandhu, Galvin, McGregor, Artz, et al., 2001). Levin (2008) described the ways in which CPGs can impact patient outcomes in nephrology through its role in education, research, and health policy development.

So, how are nephrologists fairing in the use of CPGs? Philipneri, et al. (2008) retrospectively studied administrative health records of 519 CKD patients within a private health system to ascertain CKD guideline adherence patterns of physicians. The prevalence of recommended parathyroid (PTH) testing was 7.1%, recommended phosphorus testing was 38.2%, urinary protein quantification was 10.6%, and prescription of angiotensin-converting enzyme inhibitors (ACE-inhibitors)/angiotensin II receptor blockers (ARBs) medications was 50%. Another retrospective medical record review of advanced CKD patients from 4 primary care providers and 4 nephrology private practices across the U.S. found 27% and 42% CPG adherence rates for non-nephrologists and nephrologists, respectively (Patwardhan, Matcher, Samsa, & Haley, 2008). Similarly, Charles, et al. (2009) found an adherence rate of 35% overall for both physician types.

Evidence-based guidelines provide a foundation for individualized patient care while, simultaneously, remaining based on large population-based systemic reviews of bodies of

evidence. The final decision of practitioners to follow or not follow CPGs in nephrology requires consideration of patient preferences and weighing whether exemptions or deviations from CPGs are justified (Uhlig, Balk, Lau, & Levey, 2006). In this way, evidence-based care can dually exist as patient-centered care.

Promotion of Patient Self- Management

Once the CKD patient leaves the office setting, day-to-day decisions must be made such as choosing what to eat, taking medications correctly, and following the recommended steps to slow the progression of kidney disease. As the fourth attribute, disease self-management emphasizes the patient's role in managing their illness. Patient self-management of CKD can be challenging as several interrelated chronic diseases often co-exist in a single patient (e.g., diabetes, hypertension, and CKD) requiring knowledge, skill, and motivation to successfully and simultaneously self-manage each.

The evidence of the effectiveness of self-management interventions in behavior change has been provided through multiple studies. Lorig, Ritter, et al. (2001) assessed the 1- and 2-year health status, healthcare utilization, and self-efficacy outcomes for 831 patients with heart disease, lung disease, stroke, or arthritis who participated in a Chronic Disease Self-Management Program (CDSMP). Compared to baseline data, participants revealed significant reductions in health distress ($p < .05$), increases in perceived self-efficacy ($p < .05$), and made fewer visits to physicians and the ER ($p < .05$). In a separate study, the CDSMP was used in 21 sites with 489 patients with chronic disease, classified as lung disease, heart disease, diabetes, or arthritis (Lorig, Sobel, Ritter, Laurent, & Hobbs 2001). Results shown at 1 year included statistically significant improvements in health behaviors [exercise ($p < .01$), cognitive symptom management

($p < .001$), communication with physicians ($p < .001$), self-efficacy ($p < .001$)] and health status [fatigue ($p < .003$), shortness of breath ($p < .004$), pain ($p < .04$), role function ($p < .001$), depression ($p < .001$), and health distress ($p < .001$)].

Patient Education

Provision of patient education to increase patients' knowledge levels regarding their chronic disease is the final attribute of chronic illness care. The interrelatedness of attributes is evident as knowledge is an integral component of patient self-management in the CCM.

Several studies have identified benefits of educational interventions in various stages of CKD. Benefits included a longer time to dialysis (Devins, et. al., 2003), improved survival post dialysis initiation (Devins, Mendelssohn, Barre, Taub, & Binik, et. al., 2005), improved ability to select dialysis mode prior to dialysis (Klang, Bjorvell, & Clyne, 1999), and a stabilization of the primary indicator of renal function, glomerular filtration rate (Yen, Huang, & Teng, 2008). A systematic review of educational interventions in kidney disease care revealed significant improvement in 18 of 22 studies for at least one outcome (clinical, behavioral, psychological, or knowledge) (Mason, Khunti, Stone, Farooqi, and Carr, 2008).

Boundaries of Chronic Illness Care

Nephrology providers may encounter situations in which the terms of "disease management" (DM) and a "chronic disease self-management program" (CDSMP) are used interchangeably with "chronic illness care" in CKD. Boundaries connote the separateness of one concept from other concepts, while possibly concomitantly sharing many of the same attributes in less mature concepts (Morse, Mitcham, Hupcey, & Tason, 1996). While DM, CDSMPs, and chronic illness care frequently share many of the attributes discussed above, inherent differences

separate the concepts. DM, often organized by commercial vendors, touts a cost savings to those providing care for a certain population. With the DM industry growing to over $1 billion in the U.S., evidence was found that DM improves processes of care and disease control, without conclusive evidence found to support a reduction in medical costs or an improvement in health outcomes (Mattke, Seid, & Ma, 2007). Another difference between the two concepts is the limited provider involvement in DM (Coleman, Mattke, Perrault, & Wagner, 2009). DM generally utilizes nurses or case managers to manage patient care through the use of algorithms, with little input from the provider. Based on the principles of the Arthritis Self-Management Program, CDSMPs are community-based patient self-management education programs, delivered by trained lay persons (Lorig, et al., 1999; Lorig, Ritter, et al.2001; Lorig Sobel, et al. 2001). In contrast to DM and CDSMPs, chronic illness care places the nephrology provider as a cornerstone in care delivery.

Outcomes

Outcomes are the results or the implications of the utilization of the concept (Morse, Mitcham, Hupcey, & Tasón, 1996). The potential for improved outcomes in CKD with chronic illness care using the CCM is vast. First, as opposed to sporadic segments of chronic illness care, a nephrology office organized to administer planned chronic illness care will lead to an improvement in patient care/quality of care through provider adherence to CPGs within a patient-centered approach. For instance, Healthy People 2020 objectives include an increase in the proportion of persons with diabetes and CKD who receive recommended medical treatment with ace-inhibitors or ARBs (Objective CKD 5) (Healthy People, 2020). In 2007, 54.6% of diabetic CKD persons received either an ace-inhibitor or ARB (Healthy People, 2020). A target

of 60% has been set to achieve this goal, a readily attainable goal using the CCM.

A domino effect, which begins with the re-organization to chronic illness care, will lead to the improvement in quality of CKD care. In turn, the improvement in quality of care will lead to an improvement in patient outcomes. A reduction in the morbidity and mortality rates associated with CKD is an improvement in patient outcomes that can be used for illustration purposes. Referring back to Healthy People 2020 objectives, several objectives are directly related to reducing morbidity and mortality rates in CKD patients. For example, by increasing the proportion of adult hemodialysis patients who use AV fistulas or have a maturing fistula as the primary mode of vascular access at dialysis initiation (Objective CKD 11.3) (Healthy People, 2020), morbidity and mortality rates associated with the use of catheters for dialysis are expected to plummet.

Improvement in CKD patient outcomes will affect the patients' quality of life (QOL). Next, the patients' QOL will have a direct effect on satisfaction with care, both providers and patients. Nephrology providers will feel a sense of satisfaction when chronic illness care can be adequately administered. One of the last dominoes affected by the cascade initiated by the application of the CCM is that of lower costs for CKD and ESRD for payers, Centers for Medicare and Medicaid Services (CMS), private insurers, and, ultimately, the taxpayers.

Chronic Care Model

Developed more than a decade ago, the CCM identifies 6 elements of a health care system that encourage effective chronic illness care (Chronic Care Model, 2006). The elements include: 1) organization of health care, 2) community resources, 3) delivery system design, 4) decision support, 5) clinical information systems, and 6) self-management support (Figure 3).

Health care organization is comprised of the structure, goals, and values of the provider organization, including its link with purchasers (CKD patients, HMOs), other providers, and insurers (CMS, Medicaid, and private insurance). Priorities of the organization must include chronic illness care before change in their current system of care can occur. Community resources include possible sources of referral available in the community to provide the chronic illness care that is unable to be provided within the practice. For CKD patients, this may include the NKF, vascular surgeons, diabetes educators, or dieticians. Delivery system design requires a change from the current system of care based on the acute treatment of abnormalities and patient symptoms to a planned approach for chronic illness care which utilizes a multidisciplinary team. Many nephrology practices are now providing care for CKD patients during regularly scheduled office visits based on NKF/KDOQI guidelines (every 3 months for Stage 4 CKD and every 6 months for Stage 3 CKD patients) (NKF, 2002), which is a beginning to providing chronic illness care. Multidisciplinary care varies among providers. Decision support is currently provided in nephrology through CKD clinical practice guidelines (NKF, 2002). Clinical information systems include the use of health information technology and the EMR. Use of EMRs allows for patient registries based on ICD-9 coding (e.g., identification of CKD Stage 4 patients with diabetes in a single practice), reminder systems which can signal providers when certain labs or other care is due, and feedback systems for providers to show how each provider is performing on chronic illness measures. Cost remains an issue for smaller practices to obtain EMRs. Lastly, the element of self-management support enables patients to make decisions regarding their care once they leave the office setting. Self-management can be taught within chronic illness care to enable CKD patients to make choices regarding diet; exercise; measurement of weight, blood pressure, fluid intake, and blood sugar; and medication use. The

skills of the multidisciplinary team are instrumental in teaching patient self-management.

Synthesis

The pragmatic principle of concept evaluation involves determining the "applicability of concepts to the world" or the degree to which the concept is "operationalized" (Morse, et al., 1996). When caring for patients with CKD, the application of the concept of chronic illness care is of vital importance to effectively provide quality care to this population. Differentiation of chronic illness care from chronic disease care and other interventions designed to promote various aspects of chronic illness care illuminates the inadequacies of partial change. An integrative appraisal of the literature provides the contribution of preconditions, attributes, boundaries and outcomes to clarify the concept for nephrology providers and provide a basis to apply the concept to their own practices of patient care.

Discussion

Attempts to manage the care of CKD patients, often with multiple co-existing chronic conditions, under the traditional model of medical care has led to a lower quality of care, poor outcomes, and a financial strain on current methods of medical coverage. Many indications are present signaling a need for change in the current system, hence the emergence of various models and interventions to improve CKD care. However, what is required is not a specific treatment or intervention to correct each deficiency. Rather, a total system change to a model which has demonstrated effective chronic illness care is required within the specialty of nephrology. The CCM can provide the framework to improve the chronic illness care given to CKD patients within the specialty of nephrology.

Tables and Figures

Table 2: Chronic Disease vs. Chronic Illness

Chronic Disease	**Chronic Illness**
Refers to a diagnosis categorized in the biomedical system according to etiology, pathophysiology, signs, symptoms, and treatment	Refers to the irreversible presence, accumulation, or latency of disease states or impairments that involve the total human environment for supportive care and self-care, maintenance of function, and prevention of further disability
Chronic Disease Care	**Chronic Illness Care**
Includes the treatments prescribed to lessen or control symptoms of the condition • Paternalistic form of care designed to treat the objective diagnosis • Focus is relief of symptoms and normalization of deviant physiologic measures • Usually evidence-based care	Includes systematic assessments, preventative interventions, education, psychosocial support, and follow-up • Includes chronic disease care as integral component • The lived experience of the chronic disease is treated • Form of evidence-based care

Table 3: The Concept of Chronic Illness Care

Preconditions	• Patient appointment • Provider motivation
Attributes	• Patient-centered care • Multi-disciplinary care • Evidence-based care • Patient self-management • Patient education
Boundaries	• Disease management ✓ Lack of evidence to support reduction in medical costs ✓ Evidence supports improvement in care processes and disease control ✓ Limited provider involvement ✓ $1 billion industry in U.S. • Chronic disease self-management program ✓ Self-management education using trained lay persons ✓ Community-based
Outcomes	• Improvement in patient care/quality of care • Improvement in patient outcomes • Improvement in patient quality of life • Increased satisfaction with care (both patients and providers) • Lower costs for CKD and ESRD

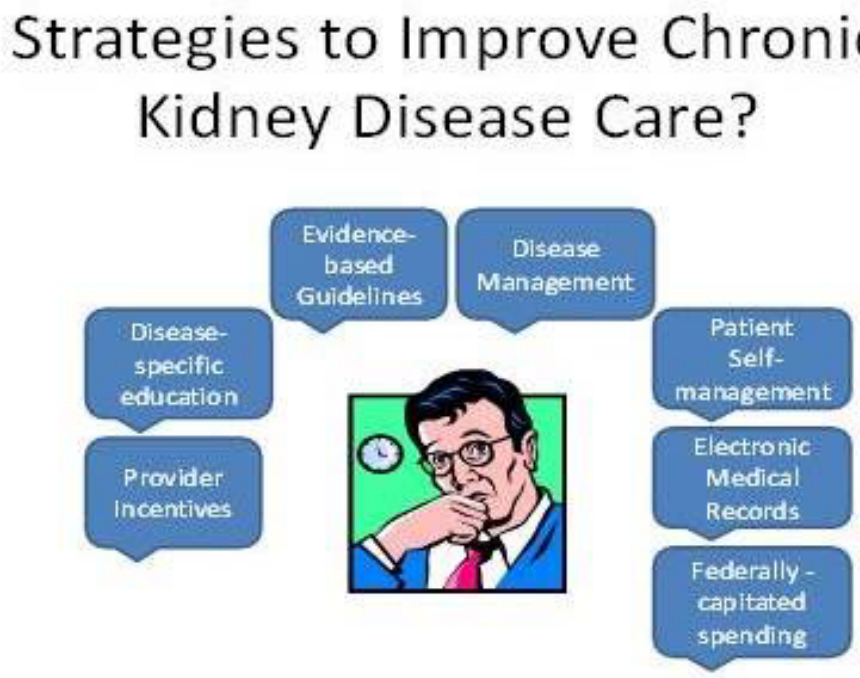

Figure 4: Models of Chronic Illness Care/Interventions

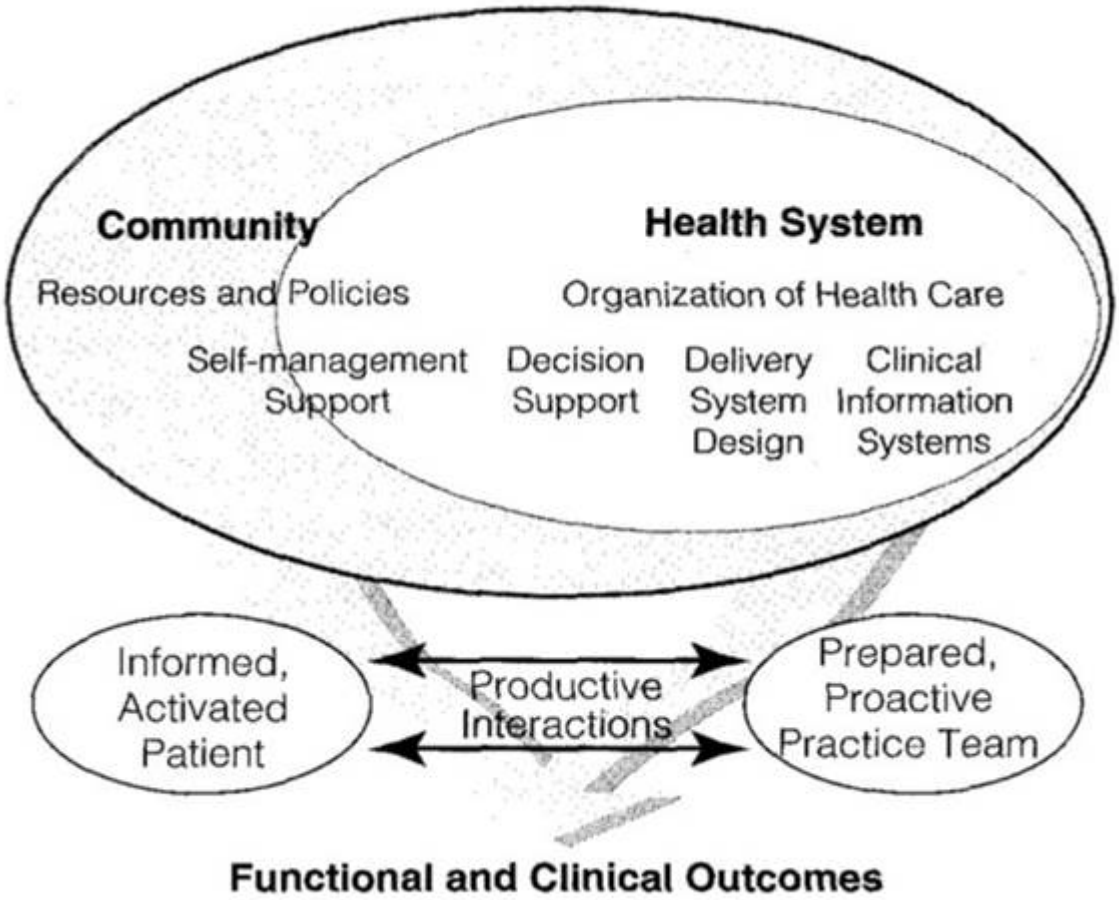

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Figure 5: The Chronic Care Model

Figure 6: Domino Effect of Chronic Illness Care Reorganization

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CHAPTER THREE: DEVELOPMENT AND PSYCHOMETRIC TESTING OF THE STAGE 4 CKD KNOWLEDGE INSTRUMENT

Abstract

The US Centers for Medicar and Medicaid Services (CMS) recognized the imperative need for improvement in predialysis education for the Stage 4 chronic kidney disease (CKD) population and instituted the Medicare Improvement for Patients and Providers Act (MIPPA) Kidney Disease Education (KDE) program in 2010. No valid and reliable method is currently in place to examine the efficacy of Stage 4 predialysis education provided to patients by nephrology physicians and advanced practitioners.

The purpose of the study was to develop and evaluate the psychometric properties of the *CKD Stage 4 Knowledge Instrument*. Instrument development was based on a literature review, National Kidney Foundation's (NKF) "Your Treatment, Your Choice" educational program for Stage 4 patients, and NKF's Kidney Disease Outcomes Quality Initiative guidelines. The 47 item measure was found to have a 7th grade reading level. Content validity was supported: item level content validity index (I-CVI) was .97 and scale level index (S-CVI) was 1.0.Reliabilty was supported: the Kuder-Richardson-20 was .89.

Study findings argue for reliability and validity of the *Stage 4 CKD Knowledge Instrument*. The instrument appears to provide a feasible method to assess patients' knowledge deficits and the efficacy of existing predialysis education programs

Introduction

Chronic kidney disease (CKD) Stage 4 is arguably the most critical stage in a CKD patient's life, in which their future course of fate is largely determined. CKD Stage 4 is also the stage in which health care providers are able to make the biggest impact and guide the patient on

the safest pathway to stage 5/end-stage renal disease (ESRD) and the treatment choice the patient wishes to pursue (Inaguma, Tatematsu, Shinjo, Suzuki, Mishima, Inaba, et al. 2006; Klang, Bjorvell, & Clyne 1999; Lacson, Wang, DeVries, Leste, Hakim, Lazarus, et al. 2011; Manns, Taub, VanderStraeten, Jones, Mills, Visser, et al. 2005, Mehrotra, Marsh, Vonesh, Peters, & Nissenson 2005) A crucial step in this journey is the predialysis education supplied by providers to patients and their families (Devins, Mendelssohn, Barre, Taub, & Binik 2005; Inaguma, et al. 2006; Lenz, Wu, Wang, Hsu, Sun, Tsai, & Wu 2009; Lacson, et al. 2011, Yen, Huang, & Teng 2008).

The US Centers for Medicare & Medicaid Services (CMS) have recognized the imperative need for intervention in the CKD Stage 4 population and have instituted the Medicare Improvement for Patients and Providers Act (MIPPA) Kidney Disease Education (KDE). This program, initiated in January 2010, provides a monetary benefit to physicians and advanced practitioners who provide comprehensive Stage 4 CKD patient education to Medicare beneficiaries (CMS Manual System, 2009). MIPPA guidelines recommend that the educational sessions should be tailored to individual needs and include information regarding management of comorbid conditions, measures to delay the need for dialysis therapy, prevention of uremic complications, and renal replacement therapy options (Centers for Medicare and Medicaid Services, 2009**).** A valid and reliable measurement tool is needed to assess Stage 4-specific CKD patient knowledge as patient education may vary from setting to setting, Nephrology providers can examine the effectiveness of their MIPPA KDE methods when equipped with such a tool.

Background

In 2009, a total of 116,395 patients began ESRD therapy. Pre-emptive transplant patients accounted for 2,759, with the remaining 113,636 initiating dialysis (USRDS, 2012). New cases of ESRD in 2009 were 355 per million population, more than 4% greater than in 2000 (USRDS, 2012), with the rate well above the Healthy People 2020 target (Centers for Disease Control and Prevention, 2010). The adjusted incidence rate of ESRD has increased 12% for patients 75 years and older, while rates for those 0 – 19 years and 20-44 have increased 9.6% and 9.8%, respectively. In comparison, incidence rates for patients 45 – 64 years and 65 – 74 years have remained relatively constant since 2000 (USRDS, 2012).

Patient CKD knowledge is a vital component necessary to slow the progression of renal disease, make necessary preparations for dialysis or transplantation, and improve CKD-related outcomes when patients have progressed to severe CKD (Stage 4). The extensive benefits of CKD education have been demonstrated multiple times. In addition to improvements in CKD knowledge (Binik, Devins, Barre, Guttman, Hollomby, Mandin, et al. 1993; Devins, Mendelssohn, Barre, & Binik 2003; King, Witten, Brown, Whitlock, & Waterman 2008; Klang, Bjorvell, & Clyne 1999; Pagels, Wang, & Wengstrom 2008; Manns, Taub, VanderStraeten, Jones, Mills, Vissner, et al. 2005; and Yen, Huang, & Teng 2008), other benefits obtained through education include: improved survival (Lacson, Wang, DeVries, Leste, Hakim, Lazarus, et al. 2011; Binik, et al. 1993, Devins, Mendelssohn, Barre, Taub, & Binik 2005; Wu, Wang, Hsu, Lee, Sun, Tsai, et al. 2009), a longer time to dialysis (Binik 1993; Devins, et al. 2003, 2005; Yen 2008), access placement prior to dialysis initiation (Hakim & Himmelfarb 2009; Lacson, et al. 2011; Levin, Lewis, Mortiboy, Faber, Hare, Porter, et al. 1997; Pagels, et al, 2008), fewer urgent dialysis starts (Levin 1997, Marron, Martinez Ocana, Salgueira, Barril, Lamas, Martin, et

al. 2005, Pagels, et al. 2008, & Ravani, Marinangeli, Stacchiotti, & Malberti, et al. 2003), improved patient outcomes post-dialysis initiation (Devins et al. 2005, Lacson, et al. 2011**),** improved self-efficacy and self-management (Manns, et al. 2005), less fluid overload and uncontrolled hypertension (Marron, et al. 2005, Pagels, et al.2008), less hospital days during the first month of dialysis (Inaguma, Tatematsu, Shinjo, Suruki, Mishima, & Inaba, et al. 2006; Levins, et al. 1997, Ravani, et al. 2003), correct patient use of medications (Pagels, et al. 2008), improved dietary management (Yen, et al. 2008), increased physical exercise (Pagels, et al. 2008), and less patient anxiety and stress (Gutierrez Vilaplana, Zampieron, Craver, & Buja 2009; King, Witten, Brown, Whitlock, & Waterman 2008).

Insufficient CKD knowledge prohibits many patients from adhering to provider recommendations. For example, CKD patients' lack of knowledge regarding prescribed medicines was shown to be independently associated with nonadherence (Moreira, Fernandes, Mota, Monte, Galvao, Sousa, et al. 2008). A qualitative study identifying key patient issues regarding blood pressure control in CKD found that patients' lack of basic knowledge was a key theme in the suboptimal levels of blood pressure control commonly observed in CKD patients (Mason, Stone, Khunti, Farooqi, & Carr 2008). In a systematic review and synthesis of qualitative studies done through October 2008, 11 of 18 studies reported that patients or their caregivers did not have the information they wanted on treatment options, regardless of whether dialysis, transplantation, or palliative care was chosen (Morton, Tong, Howard, Snelling, & Webster 2010).

Selection of hemodialyisis modality is a patient choice when options are presented prior to the need for dialysis. Finklestein, et al. (2008) found that when 676 CKD patients (Stages 3-5) in established treatment programs were asked to rate their level of knowledge regarding their

treatment options, approximately one-third of them reported no knowledge of their choices. Marron, et al. (2004) found that only half of the patients with 26 months of nephrology care prior to the initiation of dialysis were educated on dialysis modalities. Provision of predialyisis modality education has demonstrated that more patients select less-expensive home-based therapies for treatment, such as peritoneal dialysis, when given a choice (Lacson, et al. 2011; King, et al. 2006, Klang, et al. 1999, Manns, et al. 2005, Pagels, et al. 2008, & Ravani, et al. 2000).

Current CKD Knowledge Tools

As much of the medical community continues to rely on empirical verification of truths, various tests and survey have emerged to measure the effects of CKD education on patient knowledge. A limited number of valid and reliable tests have been developed to measure CKD knowledge for pre-dialysis CKD patients who range between stages 1-5 and patients in ESRD (Table 4). No instrument to measure CKD knowledge specifically in Stage 4 patients was found in the literature.

For example, Wright, Wallston, Elasy, Ikizler, & Cavenaugh (2011) developed the Kidney Knowledge Survey (KiKS) to measure knowledge about topics important to kidney disease management in Stages 1-5 pre-dialysis CKD patients. The KiKS consisted of 28 questions and was written at a sixth grade reading level. The Kuder Richardson-20 reliability coefficient of 0.72 showed good reliability of the instrument.

Devins, et al. (1990) developed a Kidney Disease Questionnaire (KDQ) for ESRD patients, available in a 26-item version or as 2 parallel 13-item multiple choice tests. The KDQ has an estimated average reading level of 9th grade and alpha reliabilities of .75 and .85 for the

parallel tests. For use in a later study, the tool was expanded to cover the pre-dialysis interval with 2 sets of new items (Devins, et al., 2003). A literature search and attempts to contact the author revealed no information on the psychometric properties of the later version.

Lastly, Curtin, Sitter, Shatell, and Chewning (2004) developed a 29-item knowledge questionnaire for dialysis patients based on previous research and on Patient Interest Checklist items from the Life Options Rehabilitation Program (1999). Alpha reliability for the questionnaire was .76. Content validity was not addressed.

Methods

Instrument Development

Item Generation

Development of the instrument was based on the literature review, the National Kidney Foundation's (NKF) "Your Treatment, Your Choice" educational program for stage 4 patients (NKF 2010), and NKF's Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines (NKF 2002). The NKF website for patients with CKD was also used as a basis for generating pertinent questions (NKF, 2010).

The measure consists of 47 items in five major categories of CKD knowledge (kidney function, associated disorders of CKD, slowing progression of CKD, CKD lifestyle, and treatment options for kidney failure), with 32 multiple-choice items and 15 true-false items (Table 2; Appendices A6, A7). A seventh grade reading level was determined using the Flesch Reading Ease Test.

Content Validity

Content validity was determined with three nephrologists and three nurse practitioners with extensive experience in treating patients with Stage 4 CKD. Experts were asked to rate each item using a 4-point scale ranging from 1= not relevant to 4= highly relevant. Item-level content validity indices (I-CVIs) were based on the ratings of the experts on each item regarding its relevance to its particular category. Responses were dichotomized into relevant (3's and 4's) and not relevant (1's and 2's). I-CVIs are considered as acceptable if they are .78 or greater (Polit, 2008). Similarly, a scale-level content validity index (S-CVI) was obtained by calculating the proportion of experts that rated an item 3 or 4 in relevance to the scale. Averaged scores of .80 or greater are considered as acceptable (Polit, 2008).

Pre-test

A convenience sample of six CKD Stage 4 patients, glomerular filtration rate (GFR) 15-29 ml/min, from a single nephrology practice participated in the pre-test. Laboratory serum creatinine levels were obtained from the electronic medical record (EMR). GFR was based on calculation using the Modification of Diet in Renal Disease (MDRD) equation. Patients with an inability to communicate in English, inability to read, or those with a documented history of memory disorders were excluded from the study. Study approval was obtained from the University of Central Florida IRB (Appedix A1).

After verbal consent (Appendix A3), the PI administered the instrument at the patients' regularly scheduled office appointments. When completed, patients gave verbal feedback on the clarity of the questions and how difficult it was for them to understand what the question was

asking. Grocery gift cards were given to participants at completion of the instrument and feedback.

Pilot Testing

A convenience sample of 59 CKD Stage 4 patients participated in the pilot testing. All particpants had a GFR of 15-29ml/min, came from a single nephrology practice, were able to communicate in English, and had no documented history of memeory disorders. After consent, subjects completed the instrument during scheduled office appointments. A grocery gift card was given to participants after completion of the instrument. The average length of time that was required for instrument completion was between 30-35 minutes.

Results

Content Validity and Pre-testing

Content validity was determined, with item level content validity index (CVI) .97 and scale level index (S-CVI) 1.0. Pretesting of the instrument determined that questions were clear and easily understood. No further changes were made to the instrument prior to pilot-testing.

Pilot Testing

The majority of participants in the pilot testing were female (n=32) and older (mean 66.7 yrs $\pm$ 11.2). The majority were Caucasian (64.4%), with African American the second largest race (18.6%) (Table 3). Education levels included less than or equal to high school (40.7%), some college (18.6%), and college degree (27.1%). The majority of participants were retired (52.5%) or disabled (22%). Most participants had Medicare coverage (53%) or private insurance (39.4%). The majority of participants' income range was $15,000-$30,000 (28.8%), followed by

those earning less than $15,000 (22%). Concurrent chronic illnesses were common. Half had coronary artery disease, 61% were diabetic, and 86% were hypertensive. Less than 20% had attended CKD education classes provided by a dialysis vendor prior to completing the knowledge instrument.

Reliability

Pilot testing revealed a mean score of 31 $\pm$ 8.2 (66.7%; SD 8.24). The KR-20 reliability coefficient was 0 .89. The mean scores for the 5 subsections of the instrument were lowest for the "Associated disorders of CKD" (56.25%, SD 23.3) and "Treatment options" (61.96%, SD 20.51). The highest score was for the subscale of "Slowing progression of CKD" (76.67%, SD 19.99) (Table 4). While a majority of patients were diabetic, diabetic questions were omitted from the statistical analysis to allow for equal comparison for all subjects.

Discussion

Findings from this study suggest that the *Stage 4 CKD Knowledge Instrument* is a valid and reliable instrument to measure CKD-specific knowledge. Testing on a larger population of CKD stage 4 patients is needed to further establish instrument reliability. Although subjects were all from one large nephrology practice, a mixed distribution of age, gender, ethnicity, education, and income levels as likely seen in other parts of the country was obtained. The high prevalence of female gender and Caucasian ethnicity in the sample is consistent with the CKD population typical of GFR<60ml/min/1.73m_2 in the NHANES population (USRDS, 2012).

Many practitioners may view the extra time that is required for patients to complete a 47-item instrument as a barrier to its application in practice. However, with proper training in test administration, it is plausible that RN's and LPN's can effectively collect this information for the

advanced practitioners and physicians after patients complete predialysis education. Participants took an average of 30-35 minutes to complete the instrument, with only one participant needing assistance due to poor eyesight.

Mean scores for the knowedge subsections revealed the lowest scores for "Associated disorders of CKD" and "Treatment options". The low scores may indicate widespread deficiencies in current patient Stage 4 education in these areas. High morbidity and mortality rates from cardiovascular disease and infection (i.e., high rates of indwelling catheter use) support this idea (USRDS, 2012). Instrument testing in Stage 4 CKD patients in other regions or states is indicated.

Future research is indicated for instrument use in other cultures and languages as differing ethnicities exist in various parts of the country. Translation and testing of the *Stage 4 CKD Knowledge Instrument* would allow for validation and use of the instrument in area-prevalent ethnicities and languages.

The *Stage 4 CKD Knowledge Instrument* is appropriate to examine patient knowledge, regardless of the teaching method employed by practitioners. A recent study evaluating the implementation of kidney disease education after the MIPPA KDE benefit began showed that approximately 40% used NKF's "Your Treatment, Your Choice" program, approximately 40% used their own program, and the remainder used a combination of the NKF program and their own slides (Zuber & Davis 2012). Although the NKF program offers an assessment of their CKD educational program, the assessment has no psychometric testing to support its use. Zuber (2012) also concluded that most practices did not use the required assessments and outcome measurements included in the NKF program.

With increased understanding of the potential impact that predialysis education has on the future outcomes of CKD patients, the availability of an instrument to measure what a patient comprehends about their disease and future choices is increasingly important. Utilization of the *Stage 4 CKD Knowledge Instrument* to accompany providers' Stage 4 kidney disease education will allow providers to evaluate and, if needed, to streamline their current teaching methods. Effective evaluation methods will lead to improvements in patients' understanding of chronic kidney disease and available options as they transition to Stage 5/ ESRD.

Tables

Table 4: Summary of Current CKD Knowledge Tools

Title of Tool	Author(s)	Target Stage(s) of Kidney Disease	# of Questions	Reading Level	Mean Score ± SD (range)	Validity	Reliability/
Kidney Disease Questionnaire (KDQ)	Devins, et al. 1990	5	26-item or 2 parallel 13-item	9th grade	XX	XX	α 0.75 & 0.85 for parallel tests
	Devins, et al. 2003	Predialysis	2 sets of new items	XX	XX	XX	XX
	Curtin, et al. 2004	ESRD (on dialysis)	29-item	XX	XX	XX	α 0.76
	Pagels, et al. 2008	Advanced renal failure (not on dialysis)	15-item	XX	XX	Yes	XX
	Yen, et al. 2008	Predialysis	20-item	XX	XX	Yes	α 0.43-0.54
Kidney Knowledge Survey (KiKS)	Wright, et al. 2011	1-5	28-item	6th grade	0.66 ± 0.15 (0.11-0.96)	XX	KR-20= 0.72
CKD Stage 4 Knowledge Instrument	Montoya, 2012	4	47-item	7th grade	31 ± 8.2 (2-44)	I-CVI .97, S-CVI 1.0	KR-20= 0.89

XX=information not supplied by author(s). Note, findings from this study have been added to the table.

Table 5: Categories of CKD Knowledge Instrument

Category	Topics Included in Category (# of items)
I. Kidney Function	(4)
II. Associated Disorders of CKD	a. Bone and Mineral Disorders (2)
	b. Cardiovascular Disease (2)
	c. Anemia (2)
	d. Electrolyte Disturbances (2)
III. Slowing Progression of CKD	a. Medication (3)
	b. BP control (3)
	c. Diabetic control (3)
	d. Nephrotoxic substances (2)
IV. CKD Lifestyle	a. Diet (Sodium, Potassium, Protein, Phosphorus, Cholesterol, Food labels) (6)
	b. Exercise (1)
	c. Smoking (3)
V. Treatment Options for Kidney Failure	a. Hemodialysis (5)
	b. Transplantation (7)
	c. Peritoneal Dialysis (4)
	d. No treatment (1)

Table 6: Demographic and Clinical Characteristics of Pilot Study Participants (n=59)

Characteristics	n (%)
Gender	
Male	27 (45.8)
Female	32 (54.2)
Ethnicity	
African American	11 (18.6)
Hispanic	5 (8.5)
Caucasian	38 (64.4)
Asian	2 (3.4)
Other	1 (1.7)
Education	
Less than high school	5 (8.5)
High school	19 (32.2)
Trade or technical school	5 (8.5)
Some college	11 (18.6)
College degree	12 (20.3)
Graduate degree	4 (6.8)
Work Status	
Employed full time	4 (6.8)
Employed part time	3 (5.1)
Homemaker	1 (1.7)
Unemployed or laid off	4 (6.8)
Income Range/year	
Less than $15,000	13 (22)
$15,001- $30,000	17 (28.8)
$30,001- $45,000	10 (16.9)
$45, 001- $60,000	9 (15.3)
More than $60,000	9 (15.3)
Comorbid disease(s)	
Diabetes mellitis	36 (61)
Hypertension	51 (86.4)
CAD	30 (50.8)
Age mean (±SD)	66.8 (± 11.2)
Insurance	
Medicaid	5 (8.5)
Medicaid HMO	2 (3.4)
Medicare	33 (55.9)
Medicare HMO	13 (22)
Medicare supplement	13 (22)
Private	23 (39)
No insurance	1 (1.7)

Table 7: Mean scores for 5 Subscales of the Stage 4 CKD Knowledge Instrument

Category	Topics Included in Category	Mean Score(%)/(SD)
Kidney function		70.42/(30.36)
Associated Disorders of CKD	• Bone and mineral disorders • Cardiovascular disease • Anemia • Electrolyte disturbances	56.25/(23.3)
Slowing Progression of CKD	• Medication • BP control • Diabetic control • Nephrotoxic substances	76.67/(19.99)
CKD Lifestyle	• Diet • Exercise • Smoking	73/(21.26)
Treatment Options for Kidney Failure	• Hemodialysis • Peritoneal dialysis • Transplantation • No treatment	61.96/(20.51)

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CHAPTER FOUR: IMPROVING CHRONIC KIDNEY DISEASE CARE WITH GROUP VISITS: A FEASIBILITY STUDY

Abstract

The purpose of this study was to investigate the feasibility of using nurse practitioner-facilitated group visits (GVs) in chronic kidney disease (CKD) Stage 4 patients within an office-based nephrology practice. A single-group, pretest-posttest design was used. A convenience sample of eight patients was enrolled. CKD-knowledge, self-efficacy, and self-management scores were collected at baseline and post-intervention. Patient satisfaction surveys were obtained. Based on Social Cognitive Theory and the Chronic Care Model, GVs consisted of five monthly visits. Elements of a usual nephrology visit were components, in addition to an interactive discussion of CKD-related topics. All participants completed the study; the attendance rate was 93%. Knowledge of CKD improved from a median of 69% to 86% (p =.012). No improvements were noted in self-efficacy (p =.230). GV satisfaction ranged from very good to excellent. The GV model is a feasible approach to increase patient knowledge and improve CKD care.

Introduction

While estimates of Chronic Kidney Disease (CKD) prevalence shows a slight decline, from 15.8 % (2001-2004) to 15.1% (2005-2008), the prevalence of recognized CKD in the Medicare population increased 3-fold between 2000 and 2009 (United States Renal Data System [USRDS], 2011). Net increases in the proportions of CKD patients from age 20 to 64 years mirrored that of the Medicare population for the same time periods in the MarketScan and Ingenix 13 populations (USRDS, 2011). Without intervention, CKD frequently progresses to end-stage renal disease (ESRD), requiring dialysis or transplantation to survive. Despite

recommendations for medications and lifestyle adjustments that delay the progression of CKD and improve CKD-related outcomes, patients with Stage 4 CKD show alarming rates of morbidity and mortality as they progress to Stage 5 CKD/end-stage renal disease (ESRD) (USRDS, 2011; National Kidney Foundation [NKF], 2010).

Once patients have progressed to Stage 4, with an estimated glomerular filtration rate (eGFR) 15-29 mL/min, the kidney disease is severe and timely preparation prior to the need for dialysis is recommended by the National Kidney Foundation (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI) (NKF, 2010). Outcomes associated with the predialysis preparation include improved patient survival and lower health care costs linked with ESRD (Collins, Foley, Gilbertson, & Chen, 2009; Schon, Blume, Niebauer, Hollenbeak, & de Lissovoy, 2007). Preparation in Stage 4 is crucial as the rate of disease progression to Stage 5 is not always predictable (NKF, 2010). If renal replacement therapy (RRT: transplantation, peritoneal dialysis, or hemodialysis) is planned, patients are encouraged to make preparations for their choice of modalities during nephrology office visits. Placement of vascular access for either hemodialysis or peritoneal dialysis prior to the need for RRT has been a goal of the Centers for Medicare and Medicaid Services (CMS), NKF, and Healthy People 2010 & 2020; however, statistics in actual practice fall well below the goal. In 2006, 82% of patients who initiated hemodialysis therapy in the US had a temporary catheter as their primary dialysis access (Hakim & Himmelfarb, 2009). This high rate of catheter use at dialysis initiation contributes to higher morbidity, mortality and costs (Stevenson, et al., 2002; Xue, Dahl, Ebben, & Collins, 2003).

Predialysis nephrology care for Stage 4 CKD patients encompasses the management of hypertension, electrolyte disturbances, fluid balance, mineral and bone disorders, nutritional requirements, lipid abnormalities, anemia, uremic symptoms, and psychosocial issues (e.g.,

relationships, monetary concerns, depression) (Ballerini & Paris, 2006; Devins, Mendelssohn, Barre, & Binik, 2003; Devins, Mendelssohn, Barre, Taub & Binik, 2005; Murphy, Jenkins, McCann, & Sedgewick, 2008). Nephrology providers must consider individual patient lifestyles, quality of life, family dynamics, economic limitations, physical limitations, cultural background, patient skill level, and levels of comprehension.

Patients' lack of knowledge, low levels of self-efficacy, and poor ability to self-manage their CKD are commonly noted in the outpatient setting and may account for the low achievement of targeted outcomes. Innovative strategies to engage Stage 4 CKD patients as active participants in their chronic disease management are needed to improve patient outcomes.

Group Visits

The group medical visit (GV) has been suggested as a novel method of providing needed chronic illness care to Stage 4 CKD patients (Young, Chan, Yevzlin, & Becker, 2011). GVs are consistent with the Chronic Care Model (CCM), promoting patient-centered, multidisciplinary, evidence-based chronic illness care (Wagner, et al., 2005). The use of GVs in a variety of other chronic diseases (e.g., diabetes and cardiovascular disease) has resulted in increased levels of patient knowledge (Trento, et al. 2001; Trento, et al., 2002; Wagner, Austin, Davis, Hindmarsh, Schaefer, & Bonomi, 2001) and self-efficacy/disease self-management (Clancy, Brown, Magruder, & Huang, 2003; Ersek, et al., 2003; Kirsh**,** et al., 2007; Scott, et al., 2004; Trento, et al., 2001; Trento, et al., 2002), leading to sustained health-related behavior change and improved patient outcomes (Trento, et al., 2001; Trento, et al., 2002, Wagner, et al. 2001; Bartley & Haney, 2010**;** Beck, et al., 1997; Blumenfeld & Tischio, 2003; Clancy, Huang, Okonofua, Yeager, & Magruder, 2007; Coleman, Eilertsen, Kramer, Magid, Beck, & Conner, 2001; De

Vries, Darling-Fisher, Thomas, & Belanger-Shugart, 2008; Loney-Hutchinson, Provilus, Jean-Louis, Zizi, Ogedegbe, & McFarlane, 2009; Maizels, Saenz, & Wirjo, 2003). The application of the GV concept in CKD offers promise of the same success. However, no studies have examined the impact of GVs on CKD. A nurse practitioner-facilitated group visit in CKD, based on Social Cognitive Theory and the CCM, was studied as an intervention that addresses Stage 4 CKD knowledge, self-efficacy, and CKD self-management, and supplies preliminary data for GVs in CKD.

Developed in the 1990's by the McColl Institute for Healthcare Innovation, the CCM provides a framework which encourages high-quality chronic disease care (Figure 1). The interdependent, essential elements of the CCM are identified as self-management support, delivery system design, decision support and clinical information systems, within a broader context of the community and health care system. Evidence-based change concepts in each element lead to productive interactions between a prepared, proactive practice team (led by the physician) and an informed and activated patient (Improving Chronic Illness Care, 2011; Wagner, Austin, & Von Korff, 1996; Wagner 1998**).**

CKD GVs are a combination of the regularly scheduled office visit with the patient's nephrologist or nurse practitioner (NP) and an interactive group discussion of CKD-related topics in a group setting. The GV is set up in two parts. In the first part, components of a usual nephrology visit are maintained, including the physical examination. During the second portion of the GV, a nephrologist, NP, or other specialist in the CKD-related topic leads a group discussion on a focused topic. The model has the potential of delivering evidence-based care to improve outcomes.

Methods

Study Design and Subjects

A single-group, pretest-posttest design was used for the study, with data collected at baseline (pre-intervention) and at five months (post- intervention). A convenience sample of eight Stage 4 CKD patients was enrolled from two participating physicians' practices in a single, large outpatient nephrology office. The patients were selected based on the ICD-9 code identified from the office computerized registry, in conjunction with the recommendation of the physician. Inclusion criteria included Stage 4 CKD (based on eGFR 15-29mL/min/1.73m^2) and age >18 years. Exclusion criteria was limited to patient disabilities which limited the patient's ability to communicate effectively within the GV setting; inability to read, write, and speak English; prior history of dialysis or transplantation; and current participation in another research study.

Procedures

Qualified patients were approached by their nephrology provider during routine medical office visist. The PI was informed of interested patients by the providers. Patients interested in participation were sent an introductory letter explaining the study.The PI followed with a phone call to interested patients one to two weeks after the letter was sent. The study was explained in greater detail during the telephone conversation and patient questions were answered.

Patients met together with the PI in the conference room at the nephrology office on one of two selected dates/ time to sign consents (Appendix B3) and to complete baseline data forms. Pretesting was completed for CKD knowledge and sef-efficacy/self-management during the visit. Participants were given $15 grocery gift cards when completed.

The CKD group visits started one week later and met monthly for a total of five GVs, on the same day of the month and time at each visit. Participants were encouraged to attend GVs with one family member. A $10 gorcery gift card was given to participants after completing the second and fourth GV.

After completion of the fifth GV, participants chose one of two dates/times to take the post-intervention CKD knowledge, self-efficacy/self-mangement, and satisfaction instruments. All instruments were administered by the PI. After data collection, a $20 grocery gift card was given to each participant.

The study was approved by the Institutional Review Board at the University of Central Florida (Appendix B1). Participants (and their family member if attending) also signed a confidentiality agreement agreeing to nondisclosure of patient information discussed within the GV setting (Appendix B4).

Group Visit Intervention

The GVs consisted of 5 monthly visits. Conducted from 4:00 pm to 6:00 pm mid-week, GVs included the 8 study participants, with 6 of the 8 participants also having a family member in attendance with them during the visit (Table 1). The first half of the GV was conducted in the office waiting area, as it has adequate space to accommodate a large number of persons and movement. There were no other patient visits scheduled for any provider during this time to minimize potential disruptions or curious onlookers. During the first hour, individual patient physical examinations were performed by the patients' nephrologist within the group setting. Per physician preference, two privacy screens were added for the exams. Laboratory data were reviewed with each patient. New prescriptions, adjustments in dose of current medications, or

refills were given based on the patient's physiological data, subjective data, and the physical exam. Referral to specialists and additional tests were ordered as necessary. Participants had the option to see the physician in a private exam room if there was an issue requiring more privacy.

After completing physical exams, the patients and family took a break to get a snack in the kitchen (provided at GV) and the bathroom if necessary. The GV reconvened in the conference room for the second portion of the GV.

The second half of the GV consisted of CKD-related education. An interactive discussion of one of five focused topics occurred at each visit, as opposed to strictly didactic lectures (Table 2). Power Point slides were used to reinforce learning during topic discussions. Each topic lasted 45 – 60 minutes. Health care professionals specializing in the topic to be covered for that visit conducted the educational portion, with the NP (investigator) present to facilitate the discussion. The participating physicians were present during the discussions as well.

At the first GV, patients were given a 3-ring notebook pre-divided into different sections. The first section was for individual patient data such as lab work, medication list, and flow sheets (blood pressure and blood glucose). The next sections were labeled with the topic of each GV. The patients were given topic information to be placed in their notebook during the educational portion of each visit. Patients brought their notebooks to all GVs. Patients were encouraged to review the topic information at home after visits.

To review the previous month's topic, patients were given paper and pencil educational games and quizzes to complete while waiting for their physical exam. The activities were constructed from material on the NKF's "Your Treatment, Your Choice" for Stage 4 CKD education and pertinent material from the previous visit's topic.

Measures and Instruments

CKD knowledge was measured with the *Stage 4 CKD Knowledge Instrument*, developed by the author (Appendices A6, A7). The measure consists of 47 items in five categories of CKD knowledge, based upon the KDOQI guidelines. A seventh grade reading level was determined. Content validity was determined, with item level content validity index (CVI) .97 and scale level index (S-CVI) 1.0. Pretesting of the instrument with six Stage 4 patients determined that the questions were clear and easily understood. The instrument was pilot tested with a sample of 29 CKD Stage 4 patients with a Kuder Richardson of .73.

Self-efficacy and self-management were measured with the 49-item *Self-Efficacy and Self-Management Behaviors in Patients with Chronic Kidney Disease* tool (Curtin, Walters, Schatell, Pennell, Wise, & Klicko, 2008) (Appendix B6). Self-management behaviors (37 items) include communication with caregivers, partnership in care, self-care, and medication adherence. The self-efficacy index includes 12 items. Alpha reliabilities for the self-management indices range from .70 to .84, and .92 for the self-efficacy index.

Satisfaction was measured in two different ways. First, a nephrology adaptation of the *General Practice Assessment Questionnaire* (Mead, Bower, & Roland, 2008) was used (Appendix B7). Minor wording changes due to language variation between the U.S. and the United Kingdom were made by the PI and questions that were not applicable were omitted. Eleven items were included in the adaption. The first eight items were coded according to a 1 through 6 Likert scale where 1= very poor through 6 = excellent. The next 3 items were coded according to a Likert scale where 1 = "the same or less than before the visits" through 3 = "much more than before the visits." Alpha reliabilities for the *GPAQ* subscales of access,

communication, and enablement were 0.86, 0.97, and 0.91, respectively (Mead et al., 2008). Space for additional comments was available at the end of the survey.

Second, an additional short satisfaction survey designed to evaluate components of the GVs was administered (Appendix B8). The survey was constructed by the PI for this study. Survey questions asked about comfort levels within the group setting, length of visits, information difficulty, future participant plans, and potential use of GVs in participants' future CKD care. Responses were rated on a scale of 1 to 5, with a higher rating indicating greater satisfaction.

Physiological measures of creatinine/eGFR, HgA1c, iPTH, phosphorus, hemoglobin, and lipid levels were obtained from the medical record to identify possible trends. Blood pressure was obtained using calibrated Hewlett-Packard electronic sphygmomanometers. Patient weights were obtained using calibrated office scales.

Statistical Analysis

Statistical analyses were conducted by using SPSS for Windows (version 16.0; Chicago, IL, 2007). Baseline data were analyzed using descriptive statistics. The nonparametric Wilcoxon signed rank test was used to compare pre- and post-intervention data for CKD knowledge, self-efficacy/self-management scores, and satisfaction. Data for the five self-management subscales were also analyzed. Physiological data were analyzed using a nonparametric Friedman test.

Results

Participation and Attrition

Study recruitment goals were achieved within six weeks. Sixteen patients who fulfilled the inclusion criteria were approached regarding participation in the study. Only 2/16 (13%)

were “not interested” in participating in GVs. Others expressed interest in the GV (5/16; 31%), but declined for various reasons. Reasons for nonparticipation included lack of transportation, upcoming major surgery, relocation north for three months in the summer, and heavy work demands during the time of the study. All interested patients who were unable to participate in the study asked to be included in the next set of GVs. Nine patients (56%) agreed to participate in the study. One who agreed to participate was unable to attend due to unplanned eye surgery the week before the first data collection visit.

Eight patients gave informed consent. All eight participants completed the study. GV attendance was 37/40 possible visits (93%). One participant “forgot” the first GV and another participant had previously scheduled trips coinciding with two GVs.

Patient Demographic and Clinical Characteristics

The majority of participants were male (n=6), older [mean 75.25 yrs $\pm$ 5.3)], Caucasian (n=7), and hypertensive (n=7). Half had diabetes. The majority were high school graduates, with three either attending college or obtaining college degrees. Household income levels included $15,000-$30,000 (n=3), $30,001-$45,000 (n=3), and $45,001- $60,000 (n=2). All participants were covered by Medicare, along with supplemental or private insurance. Two patients had attended CKD educational classes provided by a dialysis vendor prior to the study.

Knowledge

After completion of the GV intervention, knowledge of CKD improved from a median of 69% to 86%. This improvement was statistically significant: related sample Wilcoxon signed rank, p = .012. Mean percentage correct for the pretest was 65.7% ($\pm$ 14.8); posttest was 81.6% ($\pm$ 10.8).

Self-Efficacy/Self-Management

Among the self-management behaviors, only the communication index revealed an improvement in scores (Table 3). While not statistically significant, mean communication index scores showed a favorable trend upward after the GVs [17.3(± 2.9), 19.3(± 3.1); p = .08]. A statistically significant decline in self-advocacy behaviors was found [15(± 2.7), 12.3(± 1.1); p = 01]. Patients reported a high self-efficacy score at both times, with no statistically significant improvement in scores [52(± 8.0), 52.9(± 6.3); p = .23).

Satisfaction

GV satisfaction was high on the nephrology adaptation of the GPAQ. Items 1 - 8 rated different aspects of the care received during GVs, with the majority of participants responding "excellent" (59%). The next most frequent response was "very good" (31%), with "good" responses receiving 6%. Three items rated how participants felt after attending GVs in regards to the ability to understand their illness, cope with their illness, and keep themselves healthy. The majority of responses (75%) were "much more than before the visits", with 17% reporting "a little more than before the visits". Only 8% reported "the same or less than before the visits".

Participant GPAQ written comments included statements such as "I have a better knowledge about what my responsibilities are to continue to improve my care," and "This course was very informative and very well documented for people to understand. I feel concerned but not afraid to live with my problem." The spouse of a participant that attended the GVs requested to also fill out the satisfaction survey. His comments included: "The class or clinic has made my wife more prepared and aware of how each thing works with the other body parts and organs.

She has really bought into being real about her health and her mental outlook has vastly improved."

Answers to the brief eight-item satisfaction survey revealed that the majority of participants felt comfortable in the group setting for the physical exam (n=5). The length of the GVs was "just right" (n=6) and information was "easy to understand" for half the participants, with "mostly easy to understand" chosen by 3 participants. When asked if participants felt prepared to make necessary changes in their life for their kidney health, response ranged from "moderately prepared" (n=3) to "well-prepared" (n=2). Half of the participants had a "plan of action" in place if their CKD progressed. Most would recommend CKD GVs to others (n=6), with "probably would recommend" (n=1) and "might recommend" (n=1) also selected as responses. The response to the participants' future use of GVs in their CKD care was primarily for a combination of CKD GVs and regular MD office visits (n=5). Two patients selected "I would like all of my future CKD care to be in GV format" and one patient selected "Mostly CKD GVs, but occasional MD visits."

Physiological Measures

A significant difference was found for weight loss measured at the 3-month intervals (x^2 (2) = 13, p = .001), BMI ($x^2(2) = 13$, p = .001), creatinine reduction ($x^2(2) = 4.9$, p = .04), and for hemoglobin improvement ($x^2(2) = 4.9$, p = .05) (Table 4). While no statistically significant difference was found for iPTH, it is of clinical importance to note that the 6-month measurement (post-intervention) was the only mean laboratory result meeting KDOQI guideline recommendations. No significant difference was found for blood pressure, eGFR, phosphorus, or

potassium. Insufficient lipid levels and HgA1c levels were available to analyze preliminary trends.

Discussion

Several observations supported the feasibility of the CKD group visits. Recruitment goals were easily met. Retention was 100%. Patient (and family) satisfaction with GVs was high. CKD knowledge significantly improved. Examination of physiological measurements over the 6-month time frame was suggestive of significant improvements in creatinine, hemoglobin, weight, and BMI. Patient communication scores improved after attending GVs. Adherence scores remained high.

Self-efficacy scores did not show a significant improvement post intervention. However, high scores obtained in pre-intervention data remained high after GVs and did show a slight improvement. It is possible that participating physicians may have recommended their more motivated patients, creating a ceiling effect for this measure.

The other self-management indices (i.e., partnership in care, self-care behaviors, and self-advocacy) did not show improvement as hypothesized. Using interventions based on the CCM and on SCT, improvements in patient self-management of their chronic illness and self-efficacy have been demonstrated in multiple chronic disease states (Bartley & Haney, 2010**;** Lorig, et al., 2001a; Lorig, et al., 2001b; Piatt, et al., 2006; Scott, et al., 2004; Sunaert, et al., 2010; Vargas, et al., 2007). Reasons for lack of improvement in some self-management indices during the feasibility study remain unclear. Perhaps the complexity of self-managing several interrelated chronic diseases that frequently co-exist with CKD (e.g., hypertension, diabetes, and heart disease) creates a more challenging scenario for the CKD patient than those in other chronic

diseases. This suggests the number of GVs might need to be expanded before an improvement in other self-management indices can be observed.

The participating physicians and the author believed that the monthly physical exams were unnecessary in most instances, with few changes noted between monthly visits for stable patients. Planned changes to CKD GV format include continuation of the interactive discussion of monthly CKD-related topics, in combination with every 3-month physician office visits in the group setting. An option will be present at topic-discussion-only visits to see either the nephrologist or NP in attendance at the GV if the patient feels it is needed based on their symptoms or concerns.

Limitations

Limitations in the feasibility study include the small sample size and the selective sampling method. Without previous well-documented CKD GV models available, this method of sampling was felt to be necessary to attempt a trial of of GVs in nephrology. The sampling method also ensured valuable participant feedback to be used to refine future GVs.

The short time frame of the feasibility study is another limitation. Although collected data indicated improvement, the long-term effect of GVs on outcomes in CKD remains unknown.

Summary

Results of the study demonstrate that the GV model is a feasible approach to improve CKD care in the Stage 4 CKD population. With prior planning and preparation, the application of the model in an outpatient nephrology office was easily woven into the existing practice. Further research in a larger randomized sample is needed to evaluate long-term results of the GV model in CKD care.

Source of Support

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Tables and Figures

Table 8: Timing and Flow of CKD Group Visits

Time	Activity	Location
3:45 – 4:00 pm	Patients checked in and seated	Reception area
4:00 – 4:45 pm	Individual patient visits/exams with MD	Reception area
4:45 – 5:00 pm	Break for snack/restroom	Office kitchen area
5:00 – 5:45 pm	CKD-related education/discussion	Conference room
5:45 – 6:00 pm	Concluding remarks and monthly visit satisfaction surveys	Conference room

Table 9: CKD Group Visit Discussions/Stage 4

Schedule	Topic	Instructor/Facilitator
GV 1	CKD Basics (what is means, what can be expected, how to avoid or delay further injury	NP or physician as instructor/NP as facilitator
GV 2	Stage 4 CKD Diet (nutritional requirements and dietary restrictions, reading labels)	Dietician as instructor/NP as facilitator
GV 3	Medication Adherence (action of & importance of common medications used in stage 4, tips to improve adherence)	Pharmacist as instructor/NP as facilitator
GV 4	Putting Affairs in Order (advance directives, insurance and monetary concerns related to progression of disease)	Social Worker as instructor/NP as facilitator
GV 5	Dialysis Options (types of dialysis with description, dialysis access placement, timing)	NP or physician as instructor/NP as facilitator

Table 10: Summary of Self-Management and Self-Efficacy Indices

Indices	Items	Index Mean Score (SD)/ Pretest	Index Mean Score (SD)/ Posttest	Possible Range	Actual Range Pretest/ Posttest	P value (1-tailed)
Communication	8	17.3 (2.9)	19.3 (3.1)	8-32	14-23/14-24	.08
Partnership	7	16 (2.9)	16.5 (2.9)	7-28	13-22/14-19	.17
Self-care	11	32.6 (3.2)	31.7 (2.1)	11-44	27-37/30-36	.13
Self-advocacy	10	15 (2.7)	12.3 (1.1)	10-40	12-19/11-14	.01
Adherence	1	3.9 (.35)	3.7 (.76)	1-4	3-4/2-4	.33
Self-efficacy	12	52 (8.0)	52.9 (6.3)	12-60	34-57/43-58	.22

Table 11: Physiological Measurements

Measure	Mean(SD)/ Baseline	Mean(SD)/ 3 mos	Mean(SD)/ 6 mos	X^2 (df)	P (one-tailed)
SBP	124(13.6)	135(12.7)	127(13.3)	.32(2)	.10
DBP	70(12.3)	67(16.5)	66(12.6)	.93(2)	.32
Weight #	200.6(39.3)	203.8(42.2)	197.5(40.8)	13(2)	.001*
BMI	30.7(6.9)	31.2 (7.1)	30.3(7.1)	13(2)	.001*
Creatinine	2.9(.65)	2.9(.69)	2.5(.66)	4.9(2)	.04*
eGFR	21.9(3.4)	21.6(4.2)	26.7(8.8)	3.3(2)	.10
iPTH	121.6(81.2)	127.2(85.9)	92.4(39.9)	.444(2)	.40
Phosphorus	3.7(.63)	3.8(.59)	3.5(.76)	1.1(2)	.29
Potassium	4.4(.62)	4.5(.46)	4.3(.19)	1.0(2)	.30
Hemoglobin	11.1(1.1)	11.3(1.2)	11.6(1.2)	4.9(2)	.05*

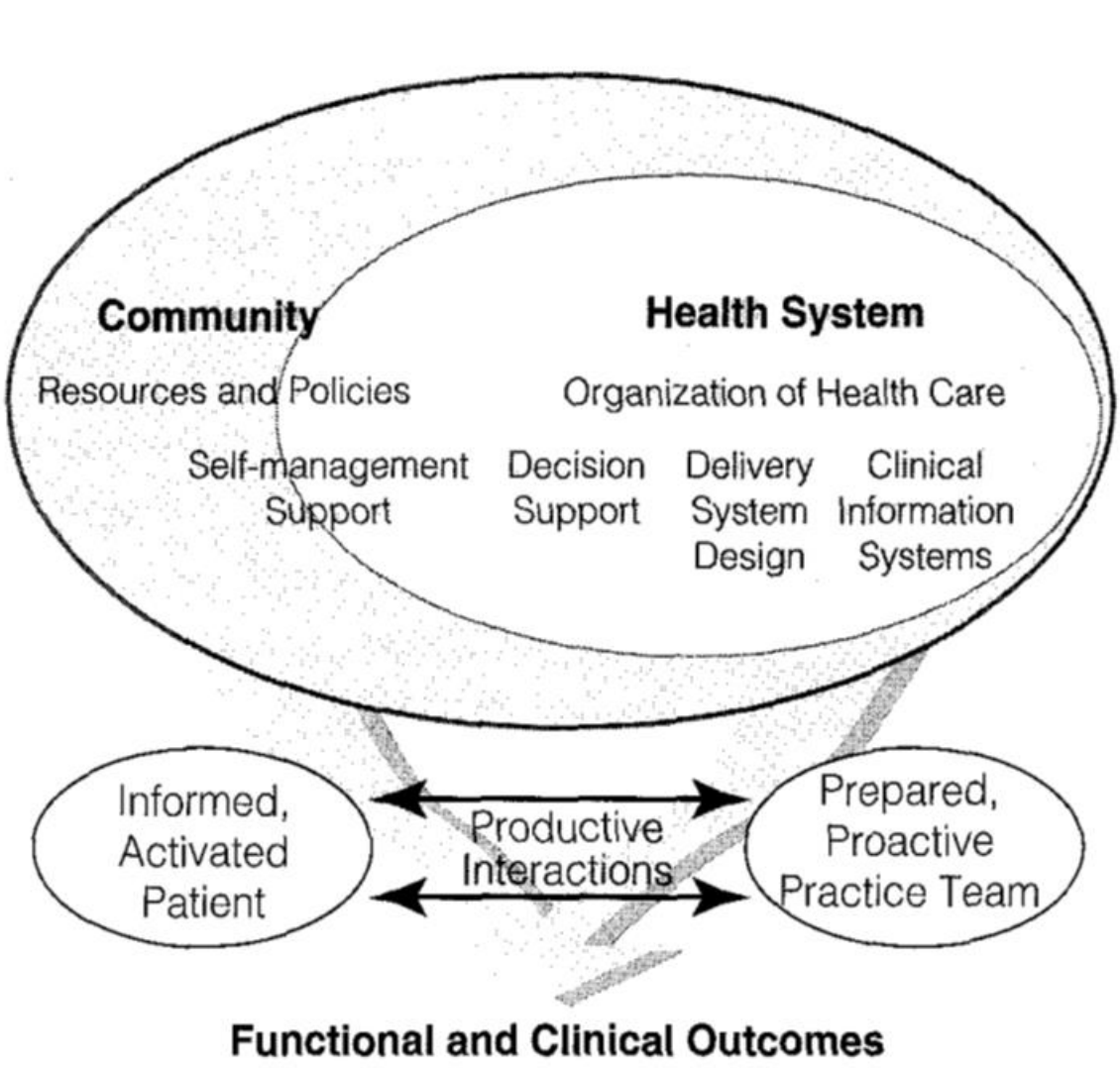

Figure 7: The Chronic Care Model

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CHAPTER FIVE: IMPROVING CHRONIC KIDNEY DISEASE CARE WITH GROUP VISITS: A PILOT STUDY

Abstract

The purpose of this study is to assess the efficacy of a nurse practitioner-facilitated chronic kidney disease (CKD) group visit (GV) model versus usual nephrology care on patient knowledge, self-efficacy, disease self-management, physiological data, and satisfaction. The design was a two-group, repeated measures experimental design, enrolling 30 Stage 4 CKD patients from an outpatient nephrology practice. Patients were randomized to the GV intervention or to usual nephrology care. Data regarding CKD knowledge, self-efficacy/self-management, and physiological measures were collected at baseline, six months, and nine months. GV satisfaction was obtained after the completion of GVs (six months). Nephrology practice satisfaction was evaluated at nine months.

Based on Social Cognitive Theory and the Chronic Care Model, GVs consisted of six monthly visits. Elements of a usual nephrology visit, including a physical examination, were components of the GV, in addition to an interactive discussion of CKD-related topics.

Twenty-six of 30 patients completed the study, with four patients ineligible to complete the study due to progression to end-stage renal disease (ESRD) and dialysis initiation. GV attendance was 92%. CKD knowledge was statistically improved for both groups ($F(1.498, 34.446) = 6.363$, $P = .008$). While not statistically significant, a favorable upward trend in the mean scores for the subscales of self-management (communication, partnership in care, and self-care) was demonstrated in the GV patients, with a lack of improvement found in the usual care group for these subscales. Self-efficacy scores revealed an improvement in mean scores for the GV patients during the GVs, not seen with usual care patients. No statistically significant

difference was found for self-efficacy. GV satisfaction was high with the vast majority of patients requesting use of GVs in their future nephrology care.

Although limited by a small sample size, promising improvements in the subscales of disease self-management, self-efficacy, CKD knowledge, and high satisfaction with the GV model were revealed in this study. Further research is warranted for the CKD GV model on a larger randomized sample to provide much needed data for use of the CKD GV in the predialysis care of Stage 4 patients.

Introduction

While the most recent reports reveal that a 14 percent improvement has occurred in first-year death rates for the end-stage renal disease (ESRD) population between 2003 and 2009, death rates remain unacceptably high. The adjusted all-cause mortality from day one in the first year of hemodialysis was 435 deaths per 1,000 patient years [United States Renal Data System (USRDS), 2012]. Adjusted rates of all-cause mortality are 6.3 - 8.2 times greater for dialysis patients than for persons in the general population. Among dialysis patients aged 65 or older, mortality rates are twice as high as the rates for patients in the general population who have cancer, diabetes, congestive heart failure (CHF), acute myocardial infarction (AMI), or cerebral vascular accident (CVA)/transient ischemic attack (TIA) (USRDS, 2012).

A search continues for effective methods to improve first year morbidity and mortality outcomes for the population transitioning from Stage 4 chronic kidney disease (CKD) to ESRD/Stage 5 CKD, requiring dialysis or transplantation. Current methods that have been employed with limited success to date include pay-for-performance incentives for nephrology providers (Desai, Garber, & Chertow, 2007; Smith & Haywood, 2011), *Fistula First*

Breakthrough Initiative for fistula placement in CKD/ESRD patients (Lynch, Mohan, and McClellan, 2011; Vassalotti, Jennings, Beathard, Neumann, Caponi, Fox, et al., 2012), improved CKD predialysis education for Stage 4 patients (National Kidney Foundation [NKF], 2010), and Kidney Disease Outcomes Quality Intiative (KDOQI) and Renal Physician's Association (RPA) provider guidelines for the treatment of CKD and its associated comorbidities (NKF, 2002; RPA, 2012). While all of these methods are evidence-based, recommendations stemming from the implementation of these methods are frequently not heeded by patients. Low levels of patient knowledge (Finklestein, Story, Firanek, Barre, Takano, Soroka, et al., 2008; King, Witten, Brown, Whitlock, & Waterman, 2008; Lewis, Stabler, & Welch, 2010; Mason, Stone, Khunti, Farooqi, & Carr, 2008; Moreira, Mota, & Sousa, 2008; Ormandy, 2008; Pagels, Wang, & Wengstrom, 2008), self-efficacy (Curtin, Walters, Schatell, Pennell, Wise, & Klicko, 2008; Wierdsma, van Zuillen, van der Bijl, 2011), and a poor ability to self-manage CKD (Byrne, Khunti, Stone, Farooqi, & Carr, 2011; Curtin, et al., 2008; Pagels, et al., 2008) are commonly noted in the outpatient setting and may account for the low achievement of targeted outcomes.

Alternately, multidisciplinary approaches to predialysis care have widespread documented success rates for improved outcomes in this population (Beaulieu & Levin, 2009; Bennett, 2007; Collister, et al., 2010; Dixon, Borden, Kaneko, & Schoolwerth, 2011; Levin, Lewis, Mortiboy, Faber, Hare, et al., 1997; Levin & Stevens, 2005; Neyhart, et al., 2010; & Spry, 2008). Levin, et al. (1997) deemed that multidisciplinary approaches would be more successful if accompanied by a supporting infrastructure and adequate resources for dedicated predialysis program staff. Following this reasoning, multidisciplinary approaches established on a supporting infrastructure, such as the Chronic Care Model (CCM) (CCM, 2006), will have a greater likelihood of improving outcomes for CKD patients. Based on the CCM, the group

medical visit (GV) has been suggested as a nontraditional multidisciplinary intervention for improving outcomes in the chronic illness care of Stage 4 patients (Young, Chan, Yevzlin, & Becker, 2011). No published studies are currently available which examine the impact of the GV intervention in Stage 4 CKD.

Background

Cardiovascular disease (CVD) and infection remain among the primary causes of mortality during the first year of dialysis (USRDS, 2012). Continued high rates of catheter use at dialysis initiation contribute to the incidence of catheter-related sepsis and early mortality. Placement of vascular access for either hemodialysis or peritoneal dialysis prior to the need for renal replacement therapy (RRT) has been a goal of the Centers for Medicare and Medicaid Services (CMS), NKF, and Healthy People 2010 and 2020 (CMS, 2012; Healthy People, 2010; Healthy People, 2020; NKF, 2002). McQuillan, et al. (2012) examined 4,807 incident hemodialysis patients from 2001-2008 to identify modifiable risk factors of early mortality using a Cox model. A majority of deaths were attributed to cardiovascular events or infection. Central venous catheter use was associated with a two to four times greater risk of death (CI: 1.4-3.9). Xue, et al. (2013) studied over 25,000 dialysis patients admitted to Fresenius outpatient dialysis centers within 15 days of the first maintenance dialysis treatment. The majority of patients initiated dialysis with a catheter (78.5%), with fistula and graft use at 16.6% and 4.9%, respectively. At 90 days, 21.9% had a fistula, 8.4% had a graft, and 69.7% still had a catheter. More than 13% of the patients had at least one positive blood culture during the first year, with a three times higher rate in patients with a catheter compared to patients with either a fistula or graft ($P < 0.001$).

As cardiovascular mortality in the CKD population remains a primary cause of mortality, efforts have been made to identify both traditional and nontraditional risk factors for CVD (Menon, Gul, & Sarnak, 2005; Sarnak, Levey, Schoolwerth, Coresh, Culleton, Hamm, et al., 2003). Traditional risk factors that exist for the general population, such as older age, male gender, hypertension (HTN), diabetes, higher levels of low density lipoproteins (LDL), and smoking, are also risk factors in the CKD population. In addition, nontraditional risk factors that play a role in CVD for patients with CKD include factors such as albuminuria, anemia, mineral and bone disorders, extracellular volume overload, electrolyte imbalance, malnutrition, and oxidative stress (Herzog, Asinger, Berger, Charytan, Diez, Hart, et al., 2011; Sarnak, et al., 2003).

Traditional and nontraditional risk factor modification for patients in predialysis stages of CKD may decrease mortality rates for those with or without progression to ESRD (Herzog, et al., 2011), as well as slow progression of CKD to ESRD requiring renal replacement therapy (RRT) (Chen, Hung, Kuo, Lee, Chiu, Chang, et al., 2013; Chue, Edwards, Davis, Steeds, Townsend, & Ferro, 2011; Schwartz, Trevedi, Kalantar-Zadeh, 2006; Voormolen, Noondzij, Grootendorst, 2007). Traditional risk factor reduction according to KDOQI guidelines is well-known in areas such as blood pressure (BP) control, diabetic control, and smoking cessation (NKF, 2002). Cholesterol management in the CKD population has been controversial; however, recent data support management of lipids. In a population-based cohort study of 2,369 CKD patients (serum creatinine $\geq$ 220umol/l), patients were further classified as primary prevention (PP) and secondary prevention (SP) cohorts in the entry data. Statin use was associated with a reduced risk of CV mortality or all-cause mortality in PP patients (HR 0.73 [CI, 0.52-0.98], HR 0.59 [CI, 0.48-0.73]) and in SP patients (HR 0.60, [CI, 0.47-0.77], HR 0.56 [CI, 0.47-0.68)]), and in SP

patients [HR 0.60, (CI, 0.47-0.77), HR 0.56 (CI, 0.47-0.68)], respectively (Sheng, Murphy, MacDonald, & Wei, 2012). A systematic review and meta-analysis of lipid-lowering therapy use in CKD examined 18 RCT involving lipid-lowering therapy to examine the effect of lipid-lowering therapy in persons with CKD (Upadhyay, Earley, Lamont, Haymes, Wanner, & Balk, 2012). Although no renal benefit was seen with lipid-lowering therapy, the risk of cardiac mortality was significantly decreased (pooled risk ratio [RR] from 6 trials, 0.82 [95% CI, 0.74-0.91], $P < 0.001$), as well as for cardiovascular events (pooled RR from 9 trials, 0.74 [CI, 0.67-0.81], $P < .001$). Recent reviews which examined the impact of statins in nondialysis CKD patients through an analysis of published studies also confirmed the cardiovascular and mortality benefit of these medications and a lack of evidence to support the use of statins as a protection against progressive CKD (Heymann, Kassimatis, & Goldsmith, 2012; Jenkins & Goldsmith, 2012).

Nontraditional risk factor modification for CKD patients is also supported in the literature. In a retrospective analysis using a logistic regression model, Jain, et al. (2012) studied 15, 803 patients with CVD treated with antihypertensive medications to determine risk factors for hyperkalemia and all-cause mortality. Compared to patients with normokalemia, patients with hyperkalemia had a higher percentage of death (6.25% vs. 2.92%, $P = 0.001$). In addition to diabetes, coronary artery disease, and peripheral vascular disease, one of the predictors of hyperkalemia was CKD stage, with Stages 3-5 included in study (odds ratio (OR) 2.14 [95% CI 2.02-2.28]). In a retrospective analysis of $> 245{,}000$ veterans, it was confirmed that the adjusted rate of hyperkalemia was higher in patients with CKD than in those without CKD among those treated with blockers of the renin-angiotension-aldosterone system (RAAS) (7.67 vs. 2.30 per 100 patient-months; $P < .001$) and those not treated with the RAAS blockers (8.22 vs 1.77 per

100 patient-months; P < .001) (Einhorn, Zhan, Hsu, Walke, Moen, Seliger, et al., 2009). The authors concluded that the risk of hyperkalemia is increased in patients with CKD, and its occurrence increases the odds of mortality within one day of the potassium elevation.

Another example of a nontraditional risk factor as a target for mortality reduction is the association between mineral and bone disorders (MBD) in CKD and CVD. The link between high serum phosphorus levels in ESRD patients and all-cause mortality and cardiovascular mortality has been supported in literature for many years (Block, 1997). More recently, MBD has been linked to predialysis stages of CKD. In a retrospective cohort study of 6,730 CKD patients, analysis revealed that serum phosphorus levels > 3.5mg/dl were associated with a significantly increased risk for death and that each 1mg/dl (0.323 mmol/L) increase in serum phosphate was associated with an estimated 23% increased risk for death (95% CI, 1.12 - 1.36) (Kestembaum, Sampson, Rudser, Patterson, Seliger, Young, et al., 2005). In a Cox multivariate adjusted regression, Eddington, et al., (2010) demonstrated that patients with Stage 3-4 CKD had an increased risk of all-cause and cardiovascular mortality in the highest quartile of phosphorus compared to the lowest quartile [HR 1.8 (95% CI, 1.1-3.1; P = 0.02], [HR 2.9 (CI, 1.3-6.4); P = 0.01].

Opportunities to reduce the impact of CVD and infection and subsequent associated mortality and morbidity begin before patients progress to ESRD. Risk factor reduction addressed in the outpatient nephrology office offers a huge potential for impact. Major barriers to achieving this goal are evident in the typical office schedules of nephrology providers. During a standard office appointment, it is unlikely that a nephrology provider can supply all the needed information and support to CKD patients to enable them to follow needed recommendations in the traditional model of care. Complexities common in the management of the CKD patient

include hypertension, electrolyte disturbances, fluid balance, mineral and bone disorders, nutritional requirements, lipid abnormalities, anemia, uremic symptoms, and psychosocial issues (e.g., relationships, monetary concerns, depression) (Ballerini & Paris, 2006; Devins, Mendelssohn, Barre, & Binik, 2003; Devins, Mendelssohn, Barre, Taub & Binik, 2005; Murphy, Jenkins, McCann, & Sedgewick, 2008). Supplying more than treatment of the chronic disease itself, multidisciplinary approaches can provide facets of patient care that are otherwise unattainable under traditional care models. Multidisciplinary interventions such as the GV can improve patient levels of disease-specific knowledge, increased levels of self-efficacy, and improve patient disease self-management in CKD as they have in other chronic diseases.

Group Visits

Although many variations exist in the literature, GVs are planned medical appointments in a group setting of usually 10-20 participants. The visits include most elements of an individual patient visit such as vital signs, history taking, and a physical exam done by a physician or nurse practitioner (NP), in addition to an educational component. Sometimes referred to as shared medical appointments, group visits differ from other types of group interventions which are generally led by peers and do not include the one-on-one consultation with the physician or NP (e.g. Chronic Disease Self-Management Programs [CDSMP]). Commonly based on a particular chronic disease, specialists in a disease-related topic, such as a dietician or physical therapist, often lead the interactive discussion within the GV.

Supported by the Institute for Healthcare Improvement (IHI) and Improving Chronic Illness Care, a national program of the Robert Woods Johnson Foundation (RWJF), the GV strategy provides chronic illness patients and their family members opportunities to assume their

own care under their provider's guidance and direction [RWJF, 2012; IHI, 2010]. GVs have been used successfully in other chronic diseases such as diabetes, CHF, HTN, and chronic obstructive pulmonary disease (COPD). Improvements in disease-specific outcomes have been demonstrated, as well as improvements in areas that enable patients to manage their chronic illness at home.

Improvements in patients' disease-specific outcomes, as noted with improvements in physiological parameters and reduction in comorbidity status, were observed in multiple GV studies (Clancy, Brown, Magruder, & Huang, 2003; De Vries, Darling-Fisher, Thomas, & Belanger-Shugart, 2008; Ersek, Turner, McCurry, Gibbons, & Kraybill, 2003; Jaber, Braksmajer, & Trilling, 2006; Kirsh, Watts, Pascuzzi, O'Day, Davidson, Strauss, et al., 2007; Maizels, Saenz, & Wirjo, 2003; Trento, Passera, Tomalino, Bajardi, Pomero, Allione, et al., 2001; Trento, Passera,Bajardi, Tomalino, Grassi, Borgo, et al., 2002). Among the improvements which equip patients to self-manage their disease, increased levels of disease-specific knowledge (Trento, et al., 2001**;** Trento, et al., 2002; Wagner, Austin, Davis, Hindmarsh, Schaefer, & Bonomi, 2001) and self-efficacy/disease self-management (Clancy, et al., 2003; Ersek, et al., 2003; Kirsh, et al., 2007; Scott, Conner, Venohr, Gade, McKenzie, Kramer, et al., 2004; Trento, et al., 2001; Trento, et al., 2002) were observed. Improvements in disease-specific knowledge, self-efficacy, and disease self-management led to sustained health behavior change and improved patient outcomes for patients enrolled in the GVs (Trento, et al., 2001; Trento, et al., 2002, Wagner, et al., 2001; Bartley & Haney, 2010; Beck, Scott, Williams, Robertson, Jackson, Gade, et al., 1997; Blumenfeld & Tischio, 2003; Clancy, Huang, Okonofua, Yeager, & Magruder, 2007; Coleman, Eilertsen, Kramer, Magid, Beck, & Conner, 2001; DeVries, et al., 2008; Loney-Hutchinson, Provilus, Jean-Louis, Zizi, Ogedegbe, & McFarlane, 2009; Maizels, et al., 2003). Also important,

patient satisfaction with GV participation was high (Beck, et al., 1997; Blumenfeld & Tischio, 2003; Clancy, et al., 2003; Coleman, Grothaus, Sandhu, & Wagner, 1999; DeVries, et al., 2008; Jaber, et al., 2006; Miller, Zantop, Hammer, Faust, & Grumbach, 2004; Scott, et al., 2004; Thacker, Maxwell, Saporito, & Bronson, 2005; and Wagner, et al., 2001).

Purpose

The purpose of this study was to assess the efficacy of a nurse practitioner-facilitated CKD group visit (GV) model versus usual nephrology care in Stage 4 CKD patients and provide baseline data for intervention use in practice. A secondary aim was to obtain effect size estimates for a larger study.

Conceptual Framework for Study

The conceptual framework for the study was the Social Cognitive Theory (SCT) (Bandura, 1986), with the Chronic Care Model (CCM) as the delivery model for the GV intervention (CCM, 2006) (Figure 8). SCT core determinants of behavior include knowledge and perceived self-efficacy (Bandura, 1986, 2004). Improvements in these core determinants are reflected in enhanced levels of disease self-management. The CCM identifies the element of patient self-management support as an integral component of successful chronic disease care, with the GV as an intervention by which self-management can be promoted.

Hypotheses

As compared to Stage 4 CKD patients who receive routine nephrology care, those who participate in the CKD GV model will:

1) Demonstrate greater levels of CKD knowledge

2) Show greater levels of self-efficacy and self-management of CKD
3) Improve achievement of target physiological endpoints: blood pressure control, lipid levels, hemoglobin A1c (HgbA1c) (if diabetic), and normovolemia
4) Show greater slowing of renal disease progression as determined by the estimated glomerular filtration rate (eGFR/creatinine)
5) Describe higher levels of satisfaction with nephrology care

Methods

A two-group, repeated measure experimental design was used, with data collected at baseline, six months, and nine months (post-intervention). The study setting was a single, large nephrology practice with 28 physicians and 11 full-time midlevel providers. Two office locations from the practice were used, with study participation from four nephrologists. A convenience sample of 30 outpatient Stage 4 CKD patients was recruited from the four supporting nephrologists. A computerized registry was used to identify potential patients based on the ICD-9 code (585.4). Inclusion criteria were age 18 or older with Stage 4 CKD, based on eGFR of 15-29 mL/min/1.73 m^2. Exclusion criteria were limited to disabilities which limit the patient's ability to communicate during the GV; inability to read, write, and speak English; history of dialysis or transplantation, or current participation in another study.

Procedures

Qualified patients were approached by the PI via telephone with a brief explanation of the study. Patients indicating interest in participating were mailed an introductory letter explaining the study in more detail. Follow-up phone calls were made to answer questions and to illicit continued interest in participation. Those indicating continued interest were mailed a consent

form minus the signature page, with dates/times options at each site included for the initial visit to collect baseline data, CKD knowledge, and self-efficacy/self-mangement surveys. Participants committed to a prescheduled date and time via a return phone call.

The participants met at their usual office location at their selected date/time to obtain written informed consent and complete baseline data forms. CKD knowledge and self-efficacy/self-management tools were completed prior to randomization. All data collection instruments were administered by the PI. Participants were given a written notation of their computer-randomized group assignment after data collection was completed. Patients were randomized to either usual care or the group visit intervention. The patients were given $15 grocery gift cards before departing.

Patients randomized to usual care continued to have nephrology care with their provider as before. Usual care paticipants received a $10 gift card for both the 3-month snd 6-month office visits with their provider.

Patients randomized to the group visit intervention met monthly at their usual nephrology office location for a total of six GVs, on the same day of the month and time at each visit. Participants were encouraged to attend GVs with one family member. A $10 grocery gift card was given to participants after completing each GV.

Participants were called with date options for the 6-month and 9-month data collection visits. For both the 6-month and 9-month data collection visits, all participants chose one of two preselected dates/times at their usual office location. The usual care patients met together with GV patients for data collection at their choice of date/time for each of the two data collection time points. All instruments were administered by the PI. After data collection, a $20 grocery gift

card was given to each participant for the six-month data collection and $25 grocery gift card for the nine-month data collection.

The study was approved by the Institutional Review Board at the University of Central Florida. Prior to the commencement of the first GV, participants randomized to the GV intervention (and their family member if present) also signed a confidentiality agreement agreeing to nondisclosure of patient information discussed within the GV setting (Appendix C1).

Treatment

Group Visit Intervention

Based on examples of various GVs in other chronic diseases, the CKD GV was developed by this investigator as a combination of the regularly scheduled office visit with the patient's nephrologist or NP and an interactive group discussion of CKD-related topics in a group setting. The GVs consisted of six monthly visits, each lasting between 1.5 to 2 hours. Conducted at each location on regularly scheduled days of the week/month and time for each site, GVs included eight study participants at each office location, with approximately half of the participants also having a family member in attendance with them during the visit. GVs at each location were arranged at times when no other patients were normally scheduled to minimize potential disruptions. Three of the six GVs were done in conjunction with the nephrologists' exams and three were educational discussions only (Figure 9).

As per standard nephrology practice, physical examinations were performed by a nephrology provider at baseline, 3 months, 6 months, and 9 months. Per physician preference, individual patients were examined in office examination rooms (as opposed to examinations in the group setting) during the first hour. Laboratory data were reviewed with each patient. New

prescriptions, adjustments in dosage of current medications, or refills were given based on the patient's physiological data, subjective data, and the physical exam. Referral to specialists and additional tests were ordered as necessary.

After nephrologists' exams, the patients and family took a break to get a snack in the kitchen (provided at GV) and the bathroom if necessary. The GV reconvened in the conference room (Site 1) or waiting room (Site 2) for the second portion of the GV.

The second half of the GV consisted of CKD-related education. An interactive discussion of 1 of 6 focused topics occurred at each visit, as opposed to strictly didactic lectures (Table 12). Power Point slides were used to reinforce learning during topic discussions. Each topic lasted 30-45 minutes. Participating nephrologists, the investigator (NP), or other health care professionals specializing in the topic to be covered for that visit conducted the educational portion, with the NP (investigator) present to facilitate the discussion. Participating nephrologists were present for the majority of discussions, as well.

At the first GV, patients were given a 3-ring notebook pre-divided into different sections. The first section was for individual patient data such as laboratory values, a medication list, and flow sheets (BP and blood glucose). The next sections were labeled with the topic of each GV. The patients were given topic information to be placed in their notebook during the educational portion of each visit. Patients brought their notebooks to all GVs. Patients were encouraged to review the topic information at home after visits.

To review the previous month's topic, patients were given paper and pencil educational games and quizzes to complete while waiting for their physical exam. The activities were constructed by the investigator from material on the NKF's "Your Treatment, Your Choice" for Stage 4 CKD education (NKF, 2010) and pertinent material from the previous visit's topic.

Usual Care

Subjects assigned to the usual care group received usual nephrology care, which includes office visits and lab work approximately every three months with their nephrology provider. CKD care is provided based on NKF/KDOQI guidelines (NKF, 2002). Visits with nephrologists are scheduled for 15-20 minutes. In the current practice setting, patients are commonly referred to CKD education classes provided by a dialysis vendor for 1-2 sessions.

Measures and Instruments

Data were collected on all patients at baseline, 6 months (after completion of GV intervention), and 9 months (to evaluate continued trend). CKD-knowledge scores, self-efficacy/self-management scores, and physiological data were obtained at baseline, 6 months, and 9 months on both groups. GV satisfaction data was collected at 6 months on intervention patients. Nephrology practice satisfaction was obtained at 9 months on both groups.

CKD knowledge was measured with the *CKD Stage 4 Knowledge Instrument*, developed by the PI (Appendices A6, A7). The measure consists of 47 items in five major categories of CKD knowledge (kidney function, associated disorders of CKD, slowing progression of CKD, CKD lifestyle, and treatment options for kidney failure), with 32 multiple-choice items and 15 true-false items. Items for the instrument were based upon NKF's "Your Treatment, Your Choice" educational program for Stage 4 patients (NKF, 2010), and NKF's KDOQI guidelines (NKF, 2002). A seventh grade reading level was determined. Content validity was determined, with item level content validity index (CVI) .97 and scale level index (S-CVI) 1.0. Pilot testing of the instrument with 59 patients revealed a KR-20 reliability coefficient of 0 .89.

Self-efficacy and self-management was measured with the 49-item *Self-Efficacy and Self-Management Behaviors in Patients with Chronic Kidney Disease* tool (Curtin, Walters, Schatell, Pennell, Wise, & Klicko, 2008) (Appendix B6). Self-management behaviors (37 items) include the subscales of: 1) communication with caregivers, 2) partnership in care, 3) self-care, and 4) medication adherence. The self-efficacy index includes 12 items. Alpha reliabilities for the self-management indices range from .70 to .84, and .92 for the self-efficacy index.

Physiological measures of creatinine, eGFR, HgbA1c, potassium, phosphorus, intact parathyroid hormone (iPTH), and lipid levels (LDL) were obtained from the medical record. BP was obtained using calibrated Hewlett-Packard electronic sphygmomanometers. Patient weights were obtained using calibrated office scales.

GV satisfaction was obtained from intervention patients using a short survey designed to evaluate components of the GVs (Appendix B8). The seven-question survey was constructed by the PI. Survey questions asked about comfort levels within the group setting, length of visits, information difficulty, future participant plans, and potential use of GVs in participants' future CKD care. Responses were rated on a scale of 1 to 5, with a higher rating indicating greater satisfaction.

A second satisfaction measure was used at nine-months. Nephrology practice satisfaction was measured for both groups using a nephrology adaptation of the *General Practice Assessment Questionnaire (GPAQ)* (Mead, Bower, & Roland, 2008), entitled the *Nephrology Practice Assessment Questionnaire* (NPAQ) (Appendix B7). Minor wording changes of the GPAQ were made by the PI due to language variation between the U.S. and the United Kingdom and questions that were not applicable were omitted to obtain the NPAQ. Eleven items were included in the adaption. The first eight items were coded according to a 1 through 6 Likert scale where

1= very poor through 6 = excellent. The next 3 items were coded according to a Likert scale where 1 = "the same or less than before the visits" through 3 = "much more than before the visits." Reliability for the NPAQ use in the study was calculated using averaged scores. Space for additional comments was available at the end of the survey.

Data Analysis

Statistical analyses were conducted by using SPSS for Windows (version 21.0; Chicago, IL). Baseline data were analyzed using descriptive statistics. Multivariate analysis of variance for repeated measures (RM-MANOVA) was computed to compare the physiological markers, self-efficacy/self-management scores, and CKD knowledge scores at baseline, six months, and nine months, and to obtain effect size estimates. Data were screened to assess assumptions of the MANOVA. Skewed data were eliminated to meet normality assumptions. Multivariate F tests were calculated to check for main and interaction effects for each outcome measure. Pillai-Bartlett trace was used as it is the most robust and post-hoc tests were run if significant effects were present. As Mauchly's test of sphericity was significant (P = .001) for the CKD knowledge, the Huynh-Feldt value was used for the small sample size. A significance level of 0.05 was used. For the second aim, the effect size of the group visits was computed.

Results

Thirty patients gave informed consent. Twenty-six of the patients completed the study, with the remaining 4 patients starting dialysis before completing the study (see also Figure 10). Fourteen patients had random assignment to usual care and 16 patients had random assignment to the GV intervention. One patient from the usual care group started dialysis and 3 patients from the intervention group started dialysis (Figure 10). GV attendance was 162/176 possible visits

(92%). Reasons for missing the GVs included illness, previously scheduled trips coinciding with GVs, lack of transportation, or "forgetting".

Demographics and Patient Characteristics

The majority of subjects were female (n=16), older (mean 68.1 years $\pm$ 10.1), Caucasian (n=18), and married (n=19) (Table 13). The majority of patients were diabetic (n=17) and hypertensive (n=27), with coronary artery disease (CAD) (n=16). Education levels were primarily a college degree (n=16) or high school graduate (n=8). Household income levels were $15,001-$30,000 (n=8), with equal number of subjects < $15,000 (n=6) and > $60,000/year (n=6). The majority of patients were covered by Medicare with supplemental policies. Few patients had attended CKD educational classes from an outside vendor prior to participation in the study (n=6).

Knowledge

The RM-MANOVA had a significant effect for within subjects ($F[1.498, 34.446] = 6.363$, $P = .008$), but not for between groups ($F[1.498, 34.446] = 1.257$, $P = .288$). Mean percentage of CKD knowledge scores improved from baseline (64.9, $\pm$ 22.6) to study completion (72.5, $\pm$ 17.8) (Table 14; Figure 11). Mean scores for the 5 categories of CKD (kidney function, associated disorders of CKD, slowing progression of CKD, CKD lifestyle, and treatment options for kidney failure) were lowest for associated disorders of CKD and for treatment options for kidney failure (Table 15). No significant effect was found for between subjects (usual care and GVs), $P = .87$. Participation in the GV intervention did not significantly influence the CKD knowledge scores.

Self-management/ Self-efficacy

Among the self-management scores, assumptions of normality were met on all subscales. A RM-MANOVA showed no significant effect for the subscales of communication, partnership in care, self-efficacy, self-care, self-advocacy, or adherence (Table 16).

While no statistical significance was found, the intervention group's mean scores for the subscales of communication, partnership in care, self-care, and self-advocacy showed a favorable upward trend not observed with the usual care group (Table 16). Mean scores for the communication and partnership in care indices found an improvement in the GV subjects from baseline to 9 months ([9.7, $\pm$ 5.1] to [12.3, $\pm$ 5.5]), ([7.6, $\pm$ 1.6] to [9.9, $\pm$ 1.3]), respectively. In comparison, the usual care subjects showed either little change in scores or a decline over time in the communication and partnership in care indices ([10.0, $\pm$ 9.5] to [10.1, $\pm$ 6.6]) ([8.1. $\pm$ 1.6] to [7.3, $\pm$ 1.3]) (Figures 12, 13). The self-care index found a likewise trend for improvement in mean scores for the intervention group from baseline to nine months ([1.8, $\pm$ 2.2] to [22.3, $\pm$ 2.1]), respectively, with a downward trend present for the usual care group (Figure 14). An improvement in self-efficacy scores was observed for the GV subjects during the intervention, but not for the usual care subjects. Both groups showed a decline at nine months for the self-efficacy index (Table 16; Figure 15).

Physiological Parameters

A RM-MANOVA showed no significant difference for any measured physiological parameter [systolic BP (SBP), diastolic BP (DBP), weight, creatinine, eGFR, phosphorus, potassium and BMI] (Table 17). There were too few data obtained for LDL levels, iPTH levels, and HgbA1c levels to be analyzed. Physiological parameters were not significantly influenced by

inclusion in the intervention group or in usual care.

Nephrology Practice Satisfaction

The nephrology adaptation of the GPAQ (NPAQ) was determined a reliable measurement of satisfaction with an alpha value of .78 in this study. Twenty-three participants completed the NPAQ survey. Items 1-8 rated different aspects of the care received during the study, with the majority of participants responding "excellent" (70%), with "very good" receiving 26%. Three items rated how participants felt after study completion in regards to the ability to understand their illness, cope with their illness, and keep themselves healthy. The majority of responses (78%) were "much more than before the visits", with 9% reporting "a little more than before the visits". Only 13% reported "the same or less than before the visits". The later 2 responses had a mixture of subjects from each group. GV responses did not differ significantly from the usual care group for the first 8 items ($X^2(1) = 5.2$, $P > .05$) or for the additional 3 items ($X^2(1) = 3.7$, $P > .05$).

GV participant written comments included statements such as "The program was very good and after completing it I have a much better understanding of my disease, how to approach the doctor with questions and concerns and use other members of the health care team for support and education," "I think this UCF study is a great idea," and "All phases of the group sessions were very informative and conducted by professionals. Very satisfactory!!"

Group Visit Satisfaction

Two patients in the GV intervention progressed to ESRD on dialysis prior to GV completion and were not eligible to complete the GV satisfaction surveys at the 6-month time; a total of 14/16 (88%) completed the survey. The seven-item satisfaction survey revealed that the

majority of participants (79%) felt comfortable enough in the group setting to ask questions or make comments, with sometimes comfortable enough to ask questions or make comments receiving 14%. Only one patient felt it was too embarrassing to say anything during the group visit. The length of the GVs was "just right" (63%), with other responses indicating that more time was needed (29%). Information was "easy to understand" for the majority of participants (71%), with "mostly easy to understand" chosen by 21%. When asked if participants felt prepared to make necessary changes in their life for their kidney health, responses ranged from "moderately prepared" (14%) to "mostly prepared" (43%) and "well-prepared" (36%). More than half (64%) of the participants had a "plan of action" in place if their CKD progressed, with others (29%) choosing "thought about it, but not sure yet". Participants would definitely recommend CKD GVs to others (93%), except one that chose "unlikely to recommend". The response to the participants' future use of GVs in their CKD care was primarily for a combination of CKD GVs and regular MD office visits (64%). Three patients (21%) selected "Mostly CKD GVs for their future care".

Discussion

The study was well-received by patients and physicians alike**.** Approximately 75% of the patients approached about study participation were interested in enrolling. Reasons for nonparticipation included lack of time, transportation issues, participation in alternate studies, or lack of interest. All enrolled patients successfully completed the study with the exception of the four patients starting dialysis prior to study completion, which automatically rendered them ineligible for continued participation. Attendance was high with a 92% attendance at the GVs. All eligible participants completed the CKD knowledge, self-efficacy and self-management tools

at all three time points. All physician visits were attended for the usual care subjects. The physician visits during the GVs were all attended with the exception of one visit for one subject.

Improvement in CKD knowledge was observed for all participants as opposed to to a greater improvement in the intervention group as hypothesized. Previous results of a single-group GV feasibility study done by this investigator showed an improvement in knowledge of CKD from a median of 69% to 86% (related sample Wilcoxon signed rank; $p = .012$). Data from the current study did not reflect the tremendous increase in CKD knowledge for either group. While improvements in CKD knowledge for the intervention patients showed an improvement from baseline to six months, the usual care patients continued to improve to nine months. While perplexing, one potential explanation for this may be that while both groups were motivated to learn at the time of enrollment, randomization prevented usual care patients from attending CKD education as offered in the GV intervention. The pre-existing motivation and increased awareness in their lack of CKD knowledge after baseline instrument completion may have inspired the usual care patients to seek knowledge via alternate methods. Another explanation may be that the continued attention through the study to usual care patients via gift cards and phone calls from the PI may have served as an additional motivator to acquire more CKD information.

Knowledge deficits in the categories of "associated disorders of CKD" and "treatment options for kidney failure" for Stage 4 patients may represent a weakness in CKD education in these areas. As other CKD knowledge instruments prior to the *Stage 4 CKD Knowledge Instrument* were not developed or validated to measure knowledge in exclusively Stage 4 patients, no formal measurement of patient knowledge in these categories is available at the time of this study for comparison. However, extrapolating from the high morbidity and mortality rates

due to catheter-related infection (as treatment options) (McQuillan, et al., 2012; Xue, et al., 2013) and CVD (as an associated disorder of CKD) (Herzog, et al., 2011; McQuillan, et al., 2012; Sarnak, et al., 2003), it is reasonable to suggest that these knowledge deficits are prevalent in Stage 4 patients.

While a statistically significant difference between the GV intervention and usual care was not observed in this study, a definite advantage was apparent for the GV patients in CKD self-management and in self-efficacy. Advantages were observed in the self-management subscales of communication (Figure 12), partnership in care (Figure 13), and in self-care (Figure 14). The self-efficacy subscale indicated a sharp improvement during participation in the GVs, not seen in the usual care group (Figure 15). A decline in self-efficacy scores was observed in the GV patients after the GVs were completed (after six months). This may reflect the importance of continued involvement with the group approach during the course of patients' nephrology care. Despite projections of a power analysis done prior to the study initiation, statistical results revealed that the study was underpowered and lacked sufficient subjects to reflect a valid statistical difference between groups. The effect size was not as large as projected in initial planning. The promising improvements in CKD self-management subscales and self-efficacy observed with GV participants in this study, as well as similar findings with GVs in other chronic diseases provide strong support for continued GV research on a larger sample.

Improvement in physiological parameters were not found as hypothesized for the patients in the GV intervention, or for the patients assigned to usual care. Mean values of BP, hemoglobin, phosphorus, and potassium for both intervention and usual care patients reflect management of these parameters according to KDOQI guidelines by the physicians. Declines in eGFR and elevations in creatinine in primarily the intervention group do not likely reflect a lack

of GV impact. Rather, the declines reveal the often unpredictable rate of progression of CKD to ESRD/Stage 5 and the crucial need to prepare patients during Stage 4 (NKF/KDOQI Guidelines, 2010). While no improvement in GFR or creatinine was observed, it is unknown if disease progression was actually slowed for some intervention patients that potentially may have progressed at a more rapid rate. Insufficient data in the parameters of HgbA1c, lipids (LDL), and iPTH may reflect a missed opportunity for modification of traditional and nontraditional risk factors by providers. Replication of the study in other regions and practices would provide a larger database to examine trends in nephrology practice.

High satisfaction with nephrology care and providers was noted with the NPAQ results. The high satisfaction with the practice is likely indicative of the perceived quality care given by the nephrologists in the study practice. In retrospect, it is not feasible to explore satisfaction differences between the two forms of care when only one group has been exposed to both types of care. It is unlikely that the usual care patients would be able to fathom the potential improvements offered through GVs without exposure to them. Patients randomized to the GV intervention had exposure to both forms of care. The GV patients indicated that they were very satisfied with the GV care and would prefer to continue with group visits in addition to their regular physician visits. Some patients indicated that they would prefer mostly group visit care with only occasional physician visits. In the single-group feasibility CKD GV study previously done, 25% of the patients indicated that they would like their future nephrology care to be in the form of group visits only. High satisfaction rates with GV care in this study are consistent with the high rates noted in other chronic diseases (Beck, et al., 1997; Blumenfeld & Tischio, 2003; Clancy, et al., 2003; Coleman, et al., 1999; DeVries, et al., 2008; Jaber, et al., 2006; Miller, et al., 2004; Scott, et al., 2004; Thacker, et al., 2005; and Wagner, et al., 2001).

Convenience sampling from two office sites within a single practice may limit the generalizability of the findings. However, the demographic results of the study participants are consistent with data from the NHANES population, showing a prevalence of female gender, age over 60 years, and Caucasian ethnicity in the CKD population with an eGFR<60ml/min/1.73m_2 (USRDS, 2012). A larger proportion of diabetes, hypertension, and CVD was present in the study than is usually seen in the NHANES CKD population (USRDS, 2012).

Although study sample size were based on a power analysis with an estimation for an alpha of .05 and a power of .80, the estimated 28 subjects were not adequate to reliably identify between group differences based on the observed power present in the statistical analysis. A randomized study on a larger sample is needed.

As the GVs were conducted only in English, generalization to other non-English speaking ethnicities is also limited. Further studies are needed to determine the effects of GVs conducted in other languages.

Insufficient data were observed in some physiological parameters. Further examination of trends in different nephrology practices is needed to evaluate for widespread deficiencies in what is considered modifiable risk factors for the Stage 4 population.

Measurement of depression in this study was not possible. However, depression has been associated with a lower quality of life and increased risk of morbidity and mortality in the CKD population (Finkelstein, Wuerth, & Finkelstein, 2010; Hedayati, Yalamanchili, & Finkelstein, 2012). As such, depression is a potential modifiable risk factor for CKD. Based on the prevalence of depression in predialysis CKD and on comments made by GV patients (and/or their family) and observations of patient interaction before and after the GVs, nephrology care delivered in the form of GVs may decrease patients' perception of isolation with their chronic

disease and provide a beneficial effect on depression. Hence, studies which assess the effect of GVs on depression in CKD are recommended for future research.

Current methods of intervention in the Stage 4 CKD population have made little impact on reducing first-year ESRD morbidity and mortality rates. Opportunities to change the poor outcomes begin in the predialysis care of Stage 4 patients. Based on the documented success of multidisciplinary approaches in predialysis care, of GVs in other chronic diseases, and of chronic illness care based on the CCM, a high probability for success exists with the application of GVs in CKD. While limited by a lack of power (small sample size), promising improvements in the subscales of disease self-management (communication, self-care, and partnership in care), self-efficacy, CKD knowledge, and a high satisfaction with the GV model were revealed in this study. Results of this pilot study suggest that further research is warranted for the CKD GV model on a larger randomized sample. Much needed data would be provided on which to base decisions regarding the use of CKD GVs in the predialysis care of Stage 4 patients, as well as its impact on reducing first-year morbidity and mortality rates.

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Tables and Figures

Table 12: CKD Group Visit Discussions/Stage 4

Schedule	Topic	Instructor/Facilitator
GV 1	CKD I/Basics (what is means, what can be expected, how to avoid or delay further injury)	NP or physician as instructor/NP as facilitator
GV 2	CKD II/Management of associated disorders of CKD, lab abnormalities, review of basics	NP or physician as instructor/NP as facilitator
GV 3	Stage 4 CKD Diet (nutritional requirements and dietary restrictions, reading labels)	Dietician as instructor/NP as facilitator
GV 4	Medication Adherence (action of & importance of common medications used in stage 4, tips to improve adherence)	Pharmacist as instructor/NP as facilitator
GV 5	Putting Affairs in Order (advance directives, insurance and monetary concerns related to progression of disease, psychosocial issues)	Social Worker as instructor/NP as facilitator
GV 6	Dialysis Options (types of dialysis with description, dialysis access placement, timing)	Physician as instructor/NP as facilitator

Table 13: Demographic and Clinical Characteristics of Pilot Study Participants

Characteristics	All Participants	Group Visit (n=16)	Usual Care (n=14) n(%)	P-value/X^2 (2-tailed)
Gender Female	16 (53.3)	9 (56.3)	7 (50)	1.0
Ethnicity				.67
African American	7(22.6)	4 (25)	3 (21.4)	
Hispanic	3 (9.7)	1 (6.3)	2 (14.3)	
Caucasian	18 (58.1)	9 (56.3)	9 (64.3)	
Asian	1 (3.2)	1 (6.3)	0	
Other	1 (3.2)	1 (6.3)	0	
Education				.69
Less than high school	4 (12.9)	2 (12.5)	2 (14.3)	
High school	8 (25.8)	6 (37.5)	2 (14.3)	
Trade or technical	2 (6.5)	1 (6.3)	1 (7.1)	
Some college	5 (16.1)	2 (12.5)	3 (21.4)	
College degree	10 (32.3)	5 (31.3)	5 (35.7)	
Graduate degree	1 (3.2)	0	1 (7.1)	
Work Status				.54
Employed full time	1 (3.2)	1 (6.3)	0	
Employed part time	1 (3.2)	0	1 (7.1)	
Disabled	6 (19.4)	2 (12.5)	4 (28.6)	
Retired	19 (61.3)	11 (68.8)	8 (57.1)	
Unemployed or laid off	2 (6.5)	1 (6.3)	1 (7.1)	
Income Range/year				*.002
Less than $15,000	6 (19.4)	1 (6.3)	5 (35.7)	
$15,001- $30,000	9 (29)	8 (50.0)		
$30,001- $45,000	4 (12.9)	3 (18.8)	1 (7.1)	
$45, 001- $60,000	5 (16.1)	0	5 (35.7)	
More than $60,000	6 (19.4)	3 (18.8)	3 (21.4)	
Comorbid disease(s)				
Diabetes mellitis	18 (58.1)	8 (50)	9 (64.3)	.48
Hypertension	28 (90.3)	15 (93.8)	12 (85.7)	.46
CAD	16 (51.6)	8 (50)	8 (57.1)	.70
Insurance				
Medicaid	3 (9.7)	2 (12.5)	1 (7.1)	.58
Medicare	21 (67.7)	10 (62.5)	11 (78.6)	.68
Private	9 (29)	6 (37.5)	3 (21.4)	.43
No Insurance	2 (6.5)	0	2 (14.3)	.22
Classes	6 (19.4)	2 (12.5)	4 (28.6)	.27
Age mean (±SD)	68.1 (± 10.1)	68.3 (± 10.0)	67.9 (± 10.6)	.92 (t-test)

Table 14: Summary of Total CKD Knowledge Scores

	Baseline Mean Score %/(SD)	6-Month Mean Score %/(SD)	9-Month Mean Score %/(SD)	P-Value
GV	70.2 (18.1)	76.2 (12.5)	75.3 (12.6)	.89 (between groups)
Usual care	70.1(10.5)	72,3 (9.9)	77.4 (10.3)	
Both groups	70.1 (13.9)	74.0 (11.0)	76.5 (11.1)	.03 (within groups)

Table 15: Summary of CKD Knowledge Scores Per Category

Category	Topics Included in Category	Baseline Mean Score (%)/(SD)	6-Month Mean Score (%)/(SD)	9-Month Mean Score (%)/(SD)
Kidney function		72.79/(26.04)	73/(28.8)	81.73/(26.03)
Associated Disorders of CKD	• Bone and mineral disorders • Cardiovascular disease • Anemia • Electrolyte disturbances	54.78/(20.42)	61.5/(26.25)	65.87/(23.6)
Slowing Progression of CKD	• Medication • BP control • Diabetic control • Nephrotoxic substances	76.1/(19.53)	78.5/(20.26)	78.37/(19.86)
CKD Lifestyle	• Diet • Exercise • Smoking	70.88/(18.81)	76/(20.62)	73.83/(13.29)
Treatment Options for Kidney Failure	• Hemodialysis • Peritoneal dialysis • Transplantation • No treatment	63.67/(16.67)	66.59/(20.29)	69.0/(21.86)

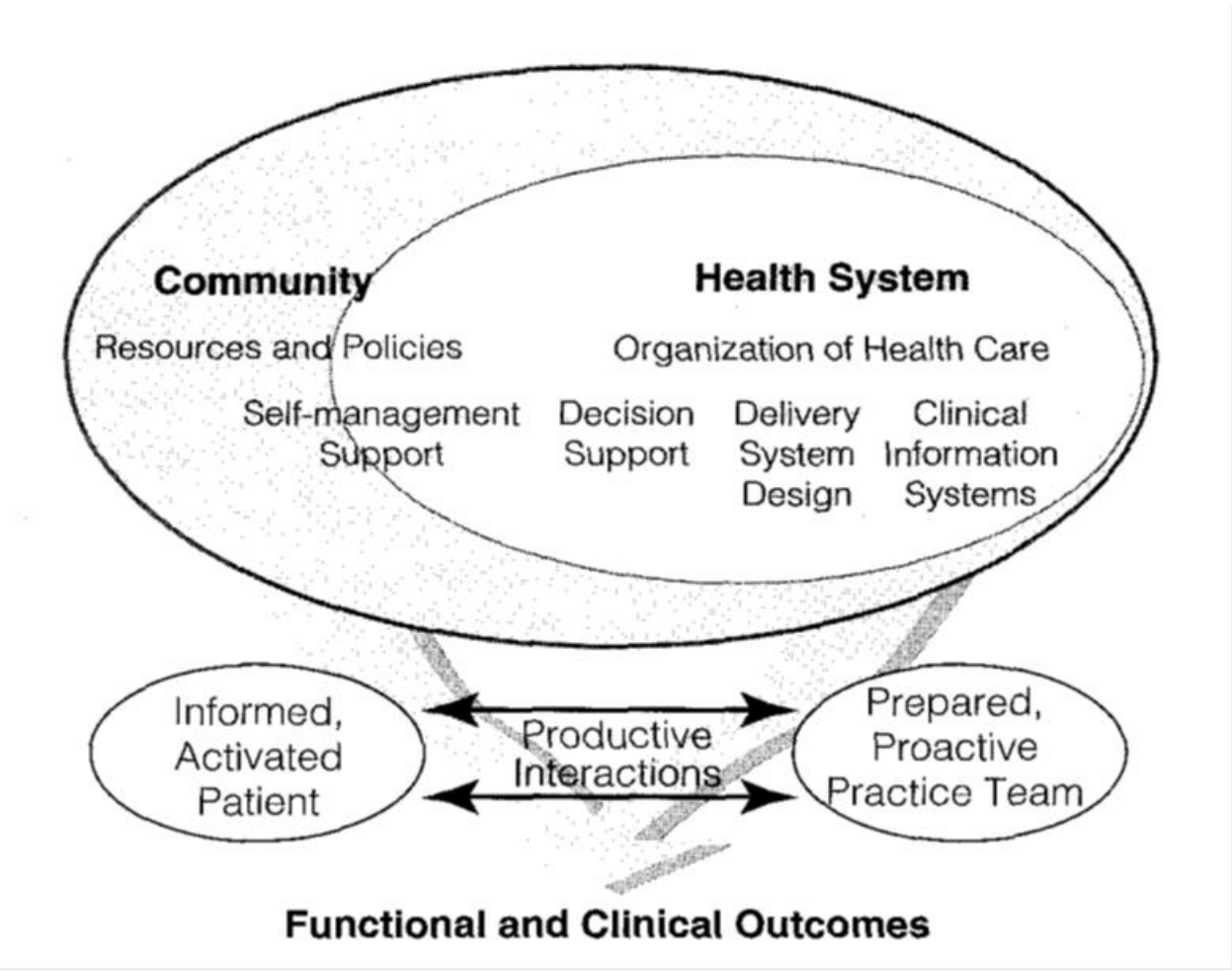
Table 16: Summary of Self-Management and Self-Efficacy Indices

Indices	Items	Index Mean Score (SD)/GV	Index Mean Score (SD)/ Usual Care	Possible Range	Actual Range Baseline/ 6 months/ 9 months	P value (1-tailed) GV/ Usual Care
Communication	8			8-32	0-21/2-18/ 1-22	.73/.54
Baseline		9.7 (5.1)	10.0 (9.5)			
6 months		11.3 (4.8)	11.3 (5.8)			
9 months		12.3 (5.5)	10.1 (6.6)			
Partnership	7			7-28	0-23/2-18/ 2-18	1.2/.28
Baseline		7.6 (1.6)	8.1 (1.6)			
6 months		10.9 (1.3)	7.9 (1.2)			
9 months		9.9 (1.3)	7.3 (1.3)			
Self-care	11			11-44	4-35/3-29/ 7-32	.41/.86
Baseline		19.8 (2.2)	21.2 (2.2)			
6 months		23.6 (1.8)	19.2 (1.7)			
9 months		22.3 (2.1)	19.6 (2.0)			
Self-advocacy	10			10-40	0-23/0-25/ 0-32	.16/.67.
Baseline		3.6 (1.3)	7.9 (1.3)			
6 months		6.1 (2.0)	6.0 (1.9)			
9 months		4.6 (2.1)	7.8 (2.0)			
Adherence	1			1-4	2-3/0-3/ 0-3	.50/.17
Baseline		3.0 (.00)	2.9 (.28)			
6 months		2.6 (1.1)	3.0 (.00)			
9 months		2.6 (1.1)	2.6 (.87)			
Self-efficacy	12			12-60	6-60/0-60/ 10-60	.84/.36
Baseline		47.3 (3.7)	45.8 (3.6)			
6 months		46.3 (4.5)	45.5 (4.4)			
9 months		39.9 (4.3)	45.2 (4.1)			

Table 17: Summary of Physiological Parameters

Parameter	Baseline Mean Value/ GV	Baseline Mean Value/ Usual Care	6 Month Mean Value/ GV	6 Month Mean Value/ Usual Care	9 Month Mean Value/ GV	9 Month Mean Value/ Usual Care	P Value (2-Tailed) Between/Within
SBP	124.6	132.9	136.2	130.5	130.4	128.8	.96/.33
DBP	72.9	68.4	80.8	70.3	76.9	70.3	.19/.13
Weight (#)	187.5	189.4	187.3	192.9	184.5	194.4	.40/.70
Creatinine	2.7	2.7	3.0	2.7	3.1	2.8	.52/.23
GFR	21.9	21.5	19.1	23.2	19.3	22.6	.28/.72
LDL	xx	xx	xx	xx	xx	xx	xx
iPTH	xx	xx	xx	xx	xx	xx	xx
phosphorus	3.3	3.7	3.4	4.0	3.2	4.3	.20/.48
potassium	4.5	4.6	4.6	4.7	4.6	4.4	.91/.76
BMI	30.4	31.8	30.7	31.5	30.9	31.2	.76/.96
Hgb	10.5	11.5	11.4	11.3	10.5	11.5	.55/.54
HgbA1c	xx	xx	xx	xx	xx	xx	xx

(SBP= systolic blood pressure, DBP=dialstolic BP, GFR= glomerular filtration rate, LDL=low density lipoproteins, iPTH= intact parthyroid hormone, BMI= body mass index, Hgb=hemoglobin, HgbA1c=hemoglobin A1c, xx= not sufficient data for analysis)



Wagner, E.H. (1998). Chronic Disease Management: What will it take to improve care for chronic illness? Effective Clinical Practice,1; Reprinted with permission.

Figure 8: The Chronic Care Model

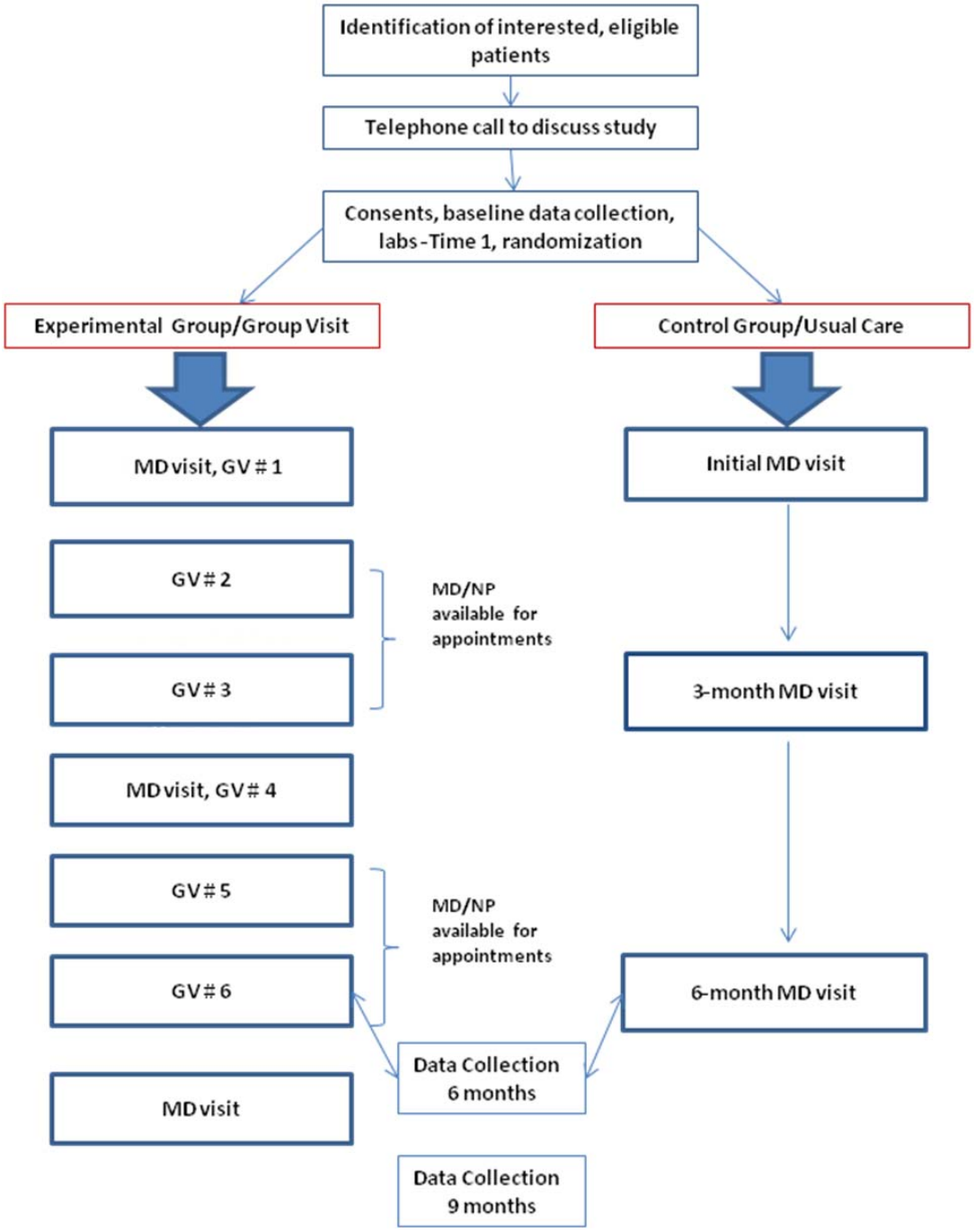


Figure 9: Group Visit Flow Chart

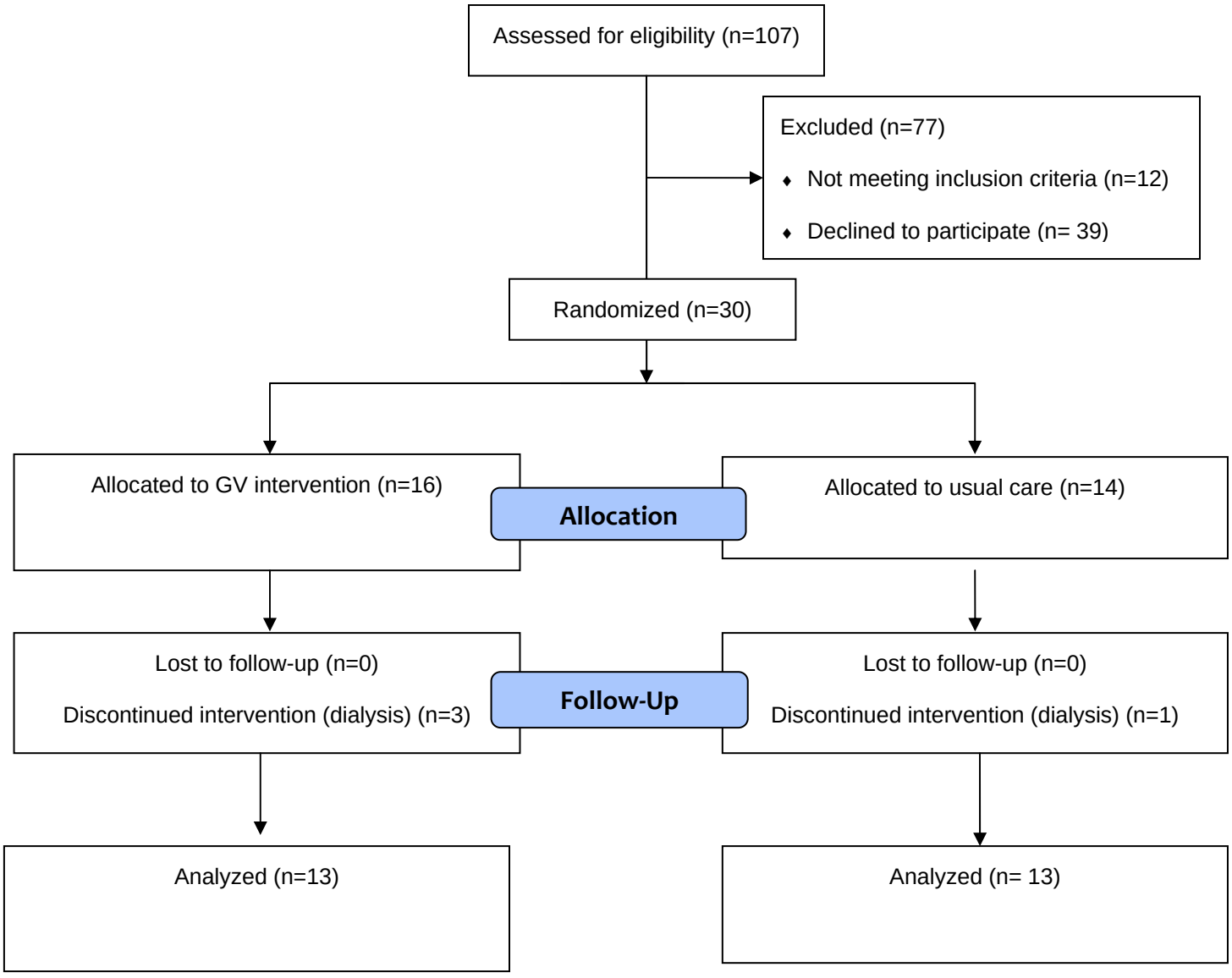


Figure 10: Pilot Group Visit Consort Flow Chart

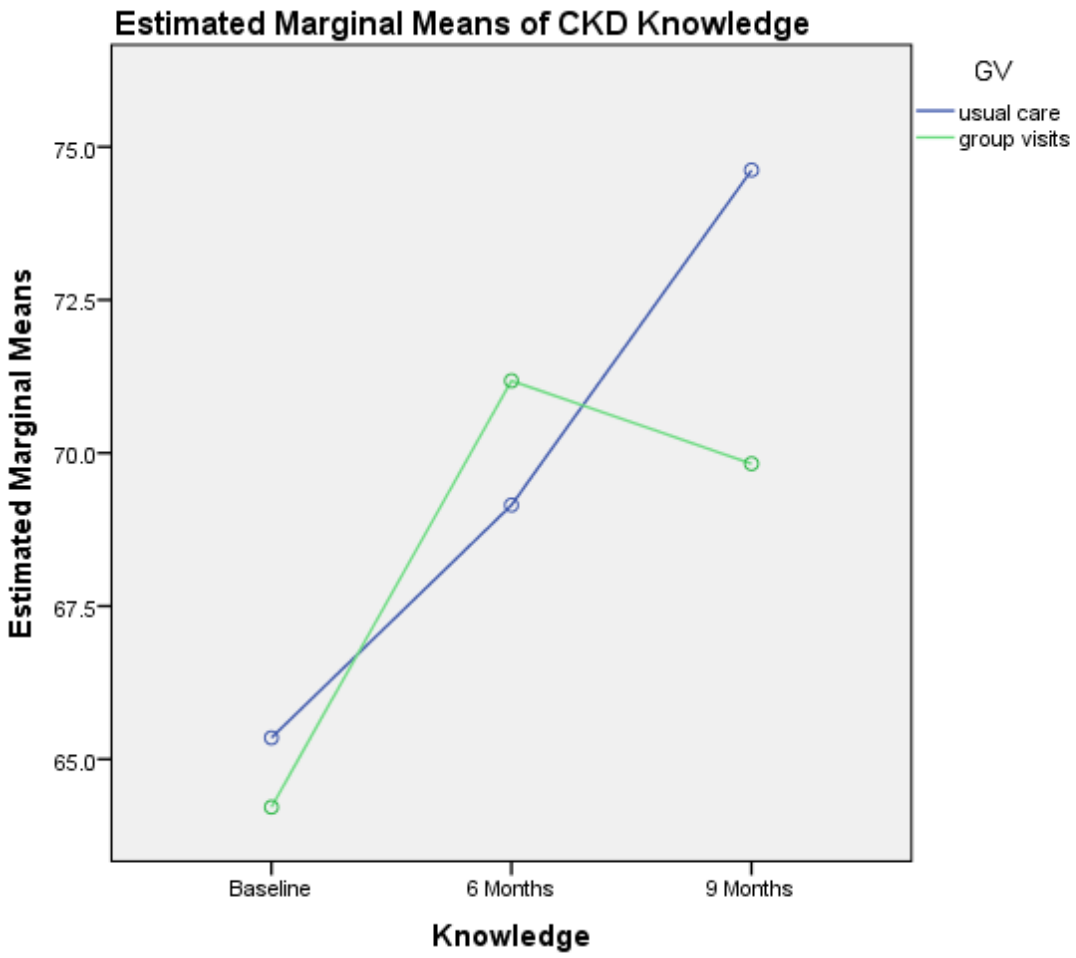


Figure 11: CKD Knowledge Scores over Time

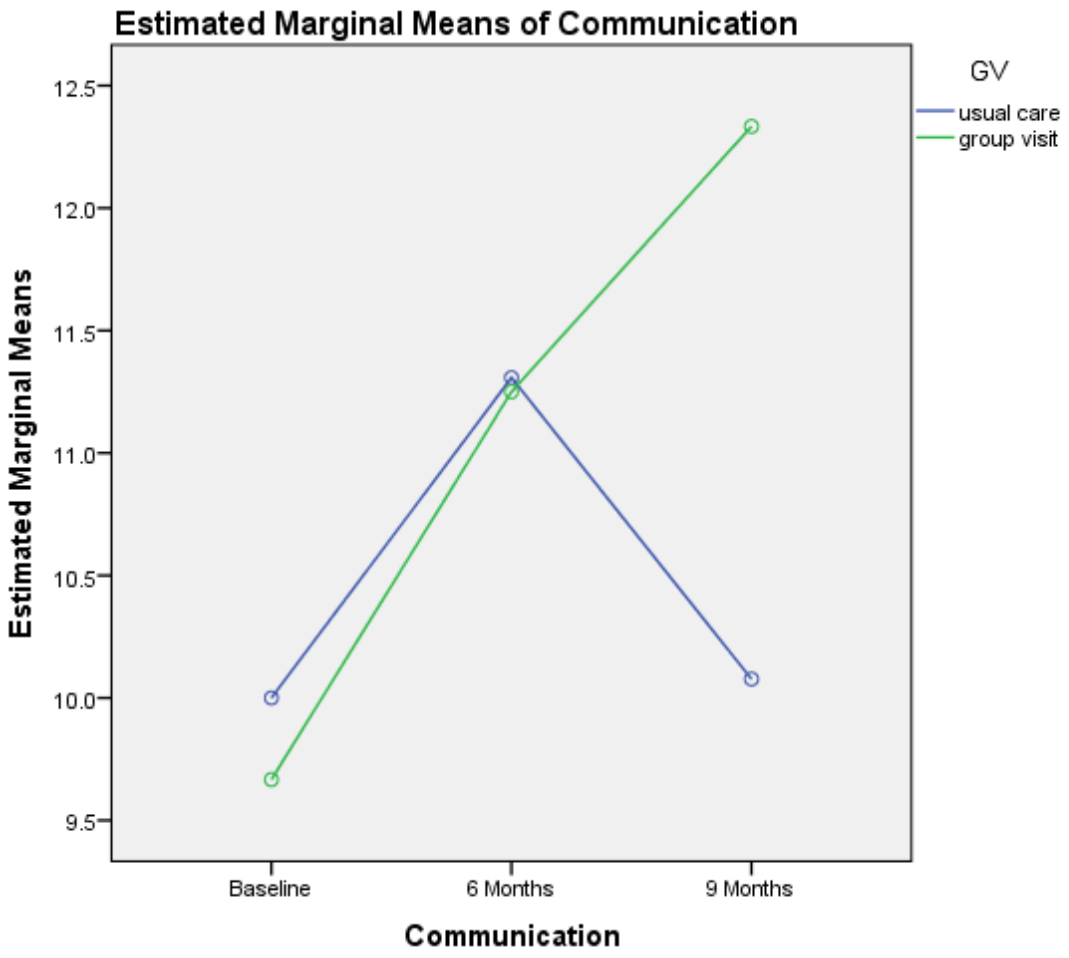


Figure 12: Communication Scores over Time

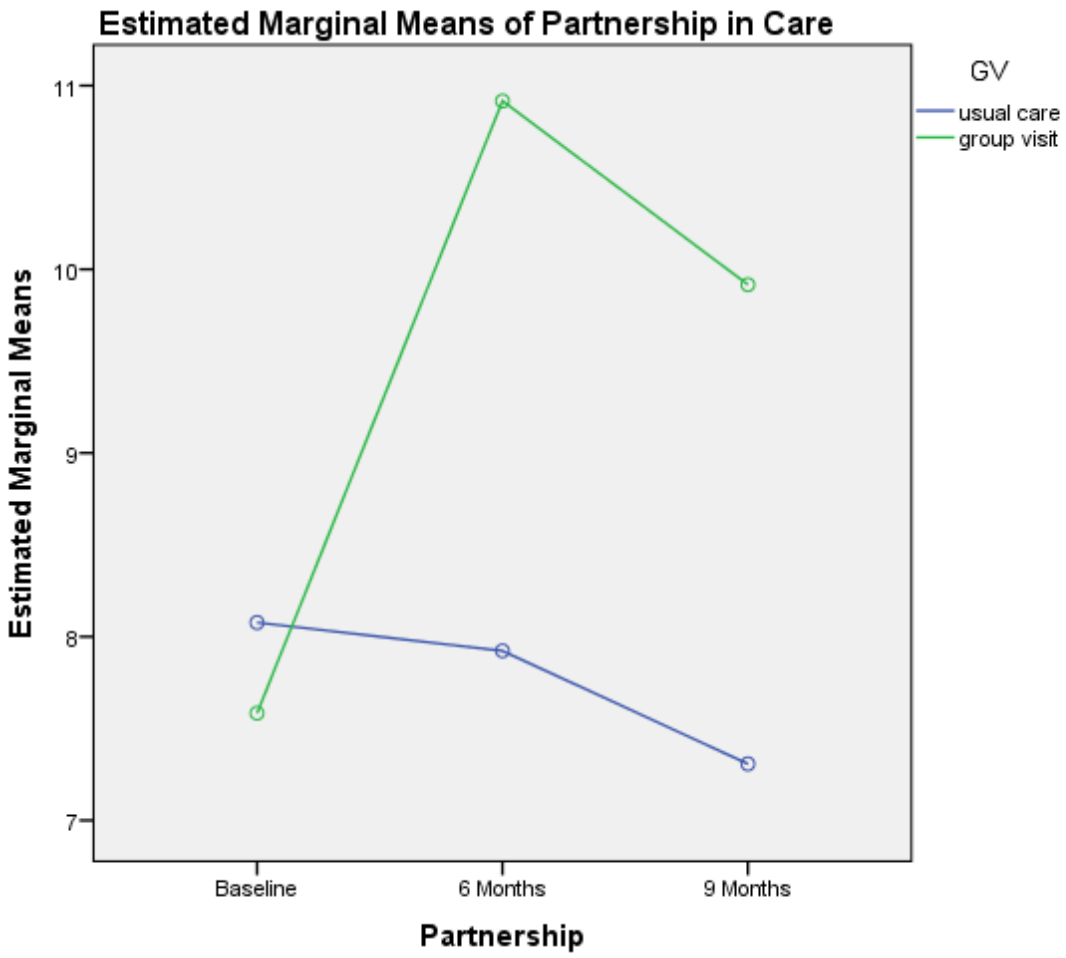


Figure 13: Partnership in Care Scores over Time

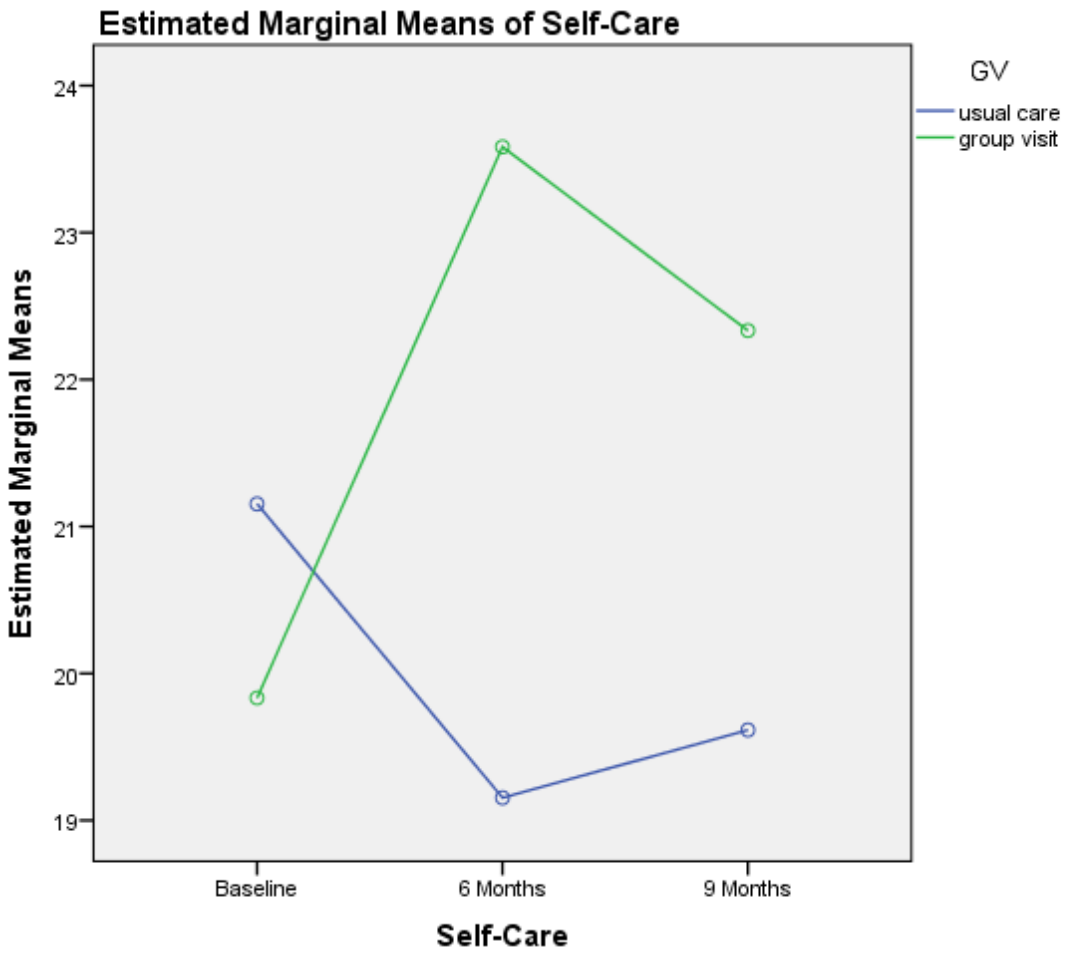


Figure 14: Self-care Scores over Time

Figure 15: Self-Efficacy Scores over Time

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