Hypertensive Chronic Kidney Disease Identification in Primary Care: A Convergent Parallel Mixed-Methods Single Embedded Case Study

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A dissertation

submitted in partial fulfillment of the

requirements for the degree of

Doctor of Philosophy

University of Washington

2018

Reading Committee:

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Program Authorized to Offer Degree:

School of Nursing

University of Washington

Abstract

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Screening rates for chronic kidney disease in high risk populations are low, leading to late diagnoses and poor patient outcomes. The goal of this dissertation was to further explore contributing factors or barriers to screening for CKD in high risk populations in primary care settings. The statement of the problem and literature review highlight the need for improvement in screening rates and offer a foundation for the three studies subsequently presented. The first study, a scoping review, was guided by the question, "How has the Chronic Care Model or its elements been applied in interventions for CKD identification or management in primary care settings, and to what degree of success?" The second study, a mixed-methods case study further explored the practices and contextual factors that are related to primary care CKD screening in a cohort of young men with hypertension within one academic medical center organization. The final study, a secondary analysis, aimed to describe current CKD guideline uptake in primary care practice related to screening and antihypertensive medication use. The dissertation concludes with overall implications for future nursing practice and research.

Acknowledgements

Over the past four years I have received support from many family members, friends, colleagues, and faculty members. First, I want to thank my husband, Tim, and our two amazing, active, adorable children Adwen and Bennett. I have been studying for most of your lives and our marriage, thank you for continuing on this journey with me and allowing me to follow my dreams. My parents and parents-in-law have been supportive, inquisitive, and loving, as have my older brothers and brothers-in-law. To my many friends who have been there to help me find balance and calm, your friendship has been invaluable. I would not have considered attempting a PhD without the superb instruction I received during the Master of Nursing program at The University of Washington Bothell. In particular, Drs. David Allen, Andrea Kovalesky, and Christopher Wade were instrumental in my decision and confidence to apply for the PhD program.

My four years at the University of Washington have been colored by many amazing faculty members and classmates throughout the School of Nursing and across the university at large. To my doctoral nursing colleagues in cohort 2014, your intelligence, capability, kindness, and motivation has been inspiring, you have each positively impacted me and I will carry that with me. The faculty member in each course I took challenged me, supported me, and guided me forward through the doctoral process. To each of my dissertation committee members, Drs. Barrington, Boutain, and Grodesky, your knowledge and expertise in your respective fields helped me to expand my view and use different lenses to view my research question, study methods, and writings.

And to Dr. Barbara Cochrane: from the day I met you prior to starting the program until now, you have buoyed me, guided me, let me find my way, and advocated for me, thank you.

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Chapter 1

Statement of the Problem

Hypertension is one of the most common chronic conditions requiring management in the primary care settings in United States (National Center for Health Statistics, 2015). Additionally, hypertension accounts for the majority of primary care visits (James et al., 2014) with about 34 million office visits per year (National Ambulatory Medical Care Survey, 2012). While almost 83% of the primary care clinicians surveyed by Lea, McClellan, Melcher, Gladstone, and Hostetter (2006) noted knowledge and use of the hypertension guidelines established by the Joint National Committee, those guidelines do not explicitly provide guidance on identification of early-stage hypertensive chronic kidney disease (CKD). Only 22 to 50% of primary care clinicians were found to be knowledgeable about or comfortable applying CKD guidelines to identify hypertensive CKD (Abdel-Kader, Greer, Boulware, & Unruh, 2014; Agrawal, Ghosh, Barnes, & McCullough, 2008; Lea et al., 2006).

The National Kidney Foundation (Vassalotti, Stevens, & Levey, 2007), the Centers for Disease Control and Prevention Chronic Kidney Disease Initiative (Centers for Disease Control and Prevention, 2015), and Healthy People 2020 Chronic Kidney Disease Objective (Healthy People 2020, 2015a) have all called for earlier identification of CKD, especially in high-risk populations such as individuals with hypertension. Studies by both Narva and Briggs (2009) and Tuot and Powe (2011) found that identification and management of early-stage hypertensive CKD is crucial to prevent or delay the progression to end-stage renal (ESRD). Currently, hypertension accounts for about one in four Americans with ESRD (United States Renal Data Systems (USRDS), 2016). Young African American men with hypertension have a faster

trajectory to ESRD (Dasmahapatra et al., 2011; Derose et al., 2013; Hall, Choi, Xu, Smith, & Boyko, 2013; Peralta et al., 2013) and start dialysis at younger ages (USRDS, 2016).

Promising results from the African American Study of Kidney Disease showed that if hypertensive kidney disease is identified and managed early, initial kidney damage (early CKD stages) can be reversed (Hu et al., 2012). Primary care clinicians, then, have the opportunity to intervene early to decrease ESRD occurrence in young African-American men. Cross-sectional studies of CKD identification by primary care clinicians have shown low recognition or documentation of CKD (Allen et al., 2011; Boulware, Troll, Jaar, Myers, & Powe, 2006; Charles et al., 2009; Plantinga, Tuot, Grubbs, Hsu, & Powe, 2012; Rao et al., 2013; Samal, Linder, Bates, & Wright, 2014); however, none of these studies used multiple methods to assess the barriers to guideline uptake or other means of CKD identification from the perspective of the provider in conjunction with assessment of actual care provision. The provider perspective is key to more fully understanding the relevant health system, organizational, and patient-based factors that support or hinder guideline uptake. Clinical practice guideline uptake occurs when care providers are aware of and in agreement with the guideline recommendations. Clinical practice guideline uptake is operationally defined as implementation of recommendations in clinical practice.

Chapter 2

Literature Review

This chapter will provide the background literature to CKD identification in primary care settings. First, the state of CKD in primary care is presented, followed by hypertension in CKD. CKD guideline implementation including a review of current guidelines is described next. Interventions that have been used to increase CKD identification will then be presented.

Chronic Kidney Disease in Primary Care

The Healthy People 2020 initiative identifies CKD as an area where bringing about change would help reduce the burden of kidney disease, help individuals with CKD live longer lives with higher quality of life, and eliminate disparities among individuals with kidney disease (Healthy People 2020, 2015b). Kidney disease is diagnosed based on laboratory results of serum estimated glomerular filtration rate (eGFR) or urine albumin-creatinine ratio (ACR) (KDIGO, 2013; National Kidney Foundation, 2002). There are five stages of CKD with the final stage known as end-stage renal disease (ESRD). While there are many causes of kidney disease, the preventable factors leading to CKD, such as diabetes and hypertension are public health problems (Collins et al., 2009; National Kidney Foundation, 2002; Vassalotti, Li, Chen, & Collins, 2009). Between 2011 and 2014, 14.8% of the National Health and Nutrition Examination Survey (NHANES) study population had CKD, with a prevalence of 16.9% amongst African Americans (USRDS), 2016). These statistics, however, may fail to adequately capture the true number of individuals with CKD. Data from the NHANES indicate that less than 10% of individuals at the initial stages of CKD are aware of their condition, and less than 50% of those with stage 4 CKD, the last stage before ESRD, were aware of their condition (Centers for Disease Control and Prevention (CDC), 2015). Additionally, in a study of rural primary care by

Rao et al. (2013), over 50% of patients who met criteria for CKD based on laboratory results did not have a diagnosis of CKD in their charts. When CKD progresses to ESRD, there is no cure. Individuals are offered either palliative care or renal replacement therapies such as dialysis or transplant. Annual Medicare expenditures for ESRD care exceed $30.9 billion (7% of Medicare expenditures) to care for less than 1% of the Medicare population (USRDS, 2015). Vassalotti et al. (2009) have asserted that we need to shift focus from ESRD management to preventing and delaying ESRD through identification and management of CKD.

Hypertensive Kidney Disease

Hypertension is a major preventable factor in CKD and ESRD. Over 30% of Americans have hypertension (National Center for Health Statistics, 2015) and approximately 25% of individuals with ESRD have a primary diagnosis of hypertension (USRDS, 2015). When reviewing those most burdened with hypertensive CKD, a disparity in identification and management are evident. While uncontrolled hypertension is most prevalent in Asian (Yoon, Fryar, & Carroll, 2015), Native American, and Hispanic (Jamerson & Townsend, 2011; Yoon et al., 2015) populations of all ages, the impact of hypertension and disease burden is highest in Native (CDC, 2014) and African American individuals (CDC, 2014; Jamerson & Townsend, 2011). Not all individuals with hypertension develop CKD, and many are not impacted until later in life. However young African American men (18-39-years old) have the highest rate of uncontrolled hypertension and are found to have a faster trajectory to ESRD (Dasmahapatra et al., 2011; Derose et al., 2013; Hall et al., 2013; Peralta et al., 2013). Indeed, young African American men with hypertension who progress to ESRD begin a renal replacement therapy, usually hemodialysis, at younger ages than other individuals with hypertension (USRDS, 2016). Also, hypertension remains the most prevalent primary diagnosis of ESRD in African American

men until age 60 when diabetes takes the lead (USRDS, 2016). Hu et al. (2012), presented promising results from the African American Study of Kidney Disease. The authors described the reversal of initial kidney damage in hypertensive kidney disease if diagnosed and managed early. This improvement in kidney function held true more often in younger African American individuals who had lower levels of proteinuria, which is an indicator of glomerular damage (Hu et al., 2012). The management of blood pressure and identification of kidney damage in hypertensive patients therefore should begin early and in the primary care setting.

Current guideline recommendations

The guidelines available for primary care clinicians to identify hypertensive CKD are cumbersome. The current literature for hypertension management does little to guide providers on early identification of target organ damage such as kidney disease. The most often cited guidelines and references for hypertension and CKD identification were reviewed for this paper; a table of those guidelines is presented in Appendix A. Hypertension guidelines from the last two Joint National Committee Recommendations on hypertension management (JNC 7; Chobanian et al., 2003; JNC 8; James et al., 2014) as well as the United States Preventive Services Task Force recommendations on hypertension screening (USPSTF, 2015) fail to outline screening for target organ damage such as kidney disease. However, both the JNC8 and the USPSTF recommendations include changes to anti-hypertensive medications based on the presence of proteinuria. Both of those guidelines also recommend different initial medications for African American individuals with hypertension than those recommended for proteinuria. Out of the United Kingdom, the National Institute for Care and Health Excellence (NICE) guidelines for hypertension (NICE, 2011) include similar medication recommendations for those of African or Caribbean descent, but also include target organ screening including urine for ACR and

hematuria and serum glucose, electrolytes, creatinine, eGFR, total cholesterol, and HDL. It is currently not reported in the literature if providers in the United States are familiar with these guidelines. Up-to-Date® is a frequently used health-care reference website. The authors of Up-to-Date®'s Overview of Hypertension page (Basile & Bloch, 2016) recommend laboratory screening of patients with hypertension to include electrolytes, creatinine (for eGFR), glucose, a urinalysis, lipids, and an EKG.

If providers access CKD specific guidelines there is better direction on testing; however, clarity about whom to test varies. The USPSTF recommendation on CKD screening (USPSTF, 2012) advises against population-level screening, but states that this recommendation does not apply to individuals with diabetes or hypertension. These recommendations also include both eGFR and urine ACR as the two tests one would order to diagnose CKD. The Kidney Disease: Improving Global Outcomes recommendations (KDIGO, 2013) are clear about staging kidney disease using both eGFR and urine ACR; however, the details on who they recommend for screening (individuals with diabetes, hypertension, cardiovascular disease, structural renal disease, lupus, hereditary kidney disease, advanced age, taking nephrotoxic medications, and/or presence of hematuria/proteinuria) are buried in introductory text of the 170-page document. The NICE guidelines for CKD screening are the same as the KDIGO for both populations and laboratory testing practices. The National Institutes of Diabetes and Digestive and Kidney Diseases alongside the National Kidney Foundation (National Institute of Diabetes and Digestive and Kidney Diseases, 2015) released guidelines for kidney disease screening as well. Those recommendations include screening individuals with diabetes, hypertension, cardiovascular disease and/or family history of kidney disease for abnormal serum eGFR and urine ACR levels. The authors of Up-to-Dates® CKD screening page (Obrador & Tonelli, 2016) identify a list of

individuals to screen over and above the KDIGO recommendations, including individuals with HIV, Hepatitis C, malignancies, recurrent urinary tract infections, all who are of Aboriginal descent (including American Indians), and/or sickle cell disease. These authors recommend both eGFR and urine ACR to identify CKD, like all the other CKD guidelines.

Hypertensive CKD in Primary Care

Primary care clinics are the first stop for most patients with chronic illnesses, with hypertension the most commonly seen condition (James et al., 2014). Health care visits by patients with hypertension account for over 34 million office visits annually (National Ambulatory Medical Care Survey, 2012). Despite the use of primary care services for hypertension management, uncontrolled blood pressure continues to be a problem. About 47% of individuals treated for hypertension are not controlled (Yoon et al., 2015), which undoubtedly represents an underestimate as it does not include individuals who are unaware of their hypertension or choose not to seek treatment. Primary care clinicians are the first line providers of CKD care (Tuot & Powe, 2011), but assessment and diagnosis for CKD is also complicated issue in primary care. Tuot and Grubbs (2015) emphasized the need for translation of the evidence about CKD into primary care practice. In a study of CKD care in rural primary practice, Rao et al. (2013) found that elevated creatinine levels on patients were not always followed up, assessment of proteinuria was low in patients with and without CKD diagnoses, and only 25% of patients with stage 4 CKD were referred to a nephrologist for further treatment. Poor awareness of guidelines and poor communication with nephrologists lead to a lack of recognition of CKD (Tuot & Powe, 2011). In a study by McBride, Dohan, Handley, Powe, and Tuot (2014), many primary care physicians were not aware of any CKD-related guidelines. Those surveyed physicians who were aware of CKD guidelines found them confusing (McBride et al., 2014).

Recent articles by Maycock and O'Callaghan (2016); Vassalotti et al. (2016); and Weber et al. (2014) have sought to translate CKD guideline recommendations of eGFR and UACR screening in high risk populations, including hypertension, for primary care clinicians.

Chapter 3

Theoretical Framework

The Chronic Care Model serves as the theoretical framework for this study (see Figure 1. below). Established by the MacColl Center for Health Care Innovation and first reported in 1998 (Wagner, 1998) with updates presented in 2003 (MacColl Center for Health Care Innovation, 2006-2016), the CCM is a multi-level framework for improving patient outcomes in those with chronic diseases. This framework has been applied to the management of many different chronic diseases and interventions (e.g.: Adams et al., 2007; Haggstrom, Taplin, Monahan, & Clauser, 2012; Jacobson & Gance-Cleveland, 2011; Pasricha et al., 2013; Stellefson, Dipnarine, & Stopka, 2013), and it provides a holistic guide for the study, identifying facilitators to quality care of individuals with chronic disease from an organizational approach.

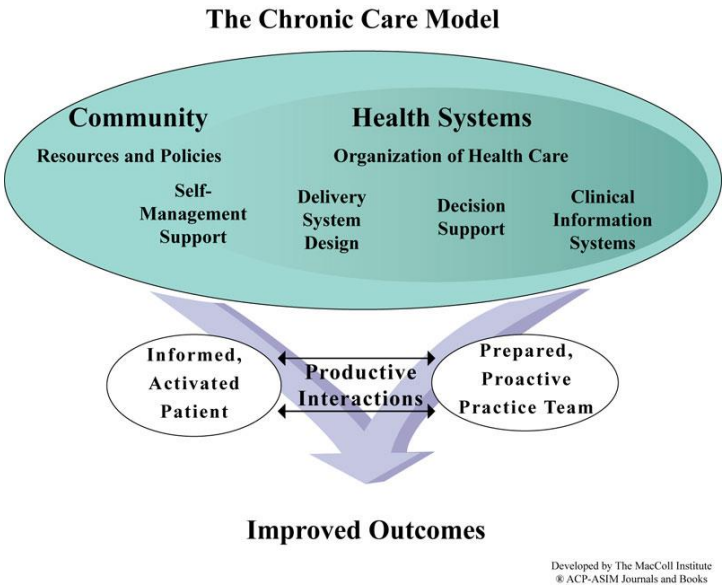

Figure 1. The Chronic Care Model (MacColl Center for Health Care Innovation, 2006-2016)

The CCM includes six elements that impact productive interactions between patients and providers(MacColl Center for Health Care Innovation, 2006-2016). The first element is the community. This element includes community resources such as non-profit organizations as well

as advocacy for policies that improve patient care. The health systems element addresses the organizational culture and mechanisms that are in place. Included in this element are senior leadership support, system change strategies, incentives for quality of care, and agreements across organizations. Within the self-management support element, patients serve a central role in health managemnt, and a collborative approach including goal setting and action planning are advised. In addition, organizationally, internal and external resources for self-management are compiled and made available. In the next element, delivery system design, roles of the various health care team members are defined and tasks are distributed. Regularly scheduled, planned interactions that support evidence-based care and that fit with the cutural background of the patient are also included in this element. Decision support, another element, marries scientific data with patient preferences. Evidence-based guidelines take a central role in this element, encouraging access to guidelines, continued education, embedding guidelines into standard practice, and sharing the evidence-based guidelines with patients. The final element, clinical information systems, focuses on the organization of data. This element includes timely feedback and reminders for providers and patients, identifying relevant sub-populations within the organization to facilitate individualized patient care planning, sharing information with patients through coordinated care, and monitoring performance quality of the practice team and the health care system. The authors of the CCM posited that when all six elements are represented within an organization, a productive interaction between the patient with a chronic illness and the health care team will lead to improved patient outcomes.

Chapter 4

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Chapter 5

The Chronic Care Model, Kidney Disease, and Primary Care: A Scoping Review

Primary care providers are often the first line sources of chronic kidney disease (CKD) care (Tuot & Powe, 2011), but assessment, diagnosis, and management of chronic kidney disease has been a complicated issue for primary care settings. Nephrology nurses have seen patients with late or no referral from primary care settings prior to end-stage renal disease (ESRD). Nephrology nurses also understand the limited resources in nephrology clinics and the burden of inappropriate referrals. Education for primary care providers alone may not be sufficient to effect change. Multifaceted interventions aimed at improving care for patients with kidney disease seen in primary care settings may help to eliminate or reduce these issues.

For example, the Chronic Care Model (MacColl Center for Health Care Innovation, 2006-2016) has been presented as a means to improve care for patients with chronic diseases utilizing a wholistic approach. This scoping review, using guidance by the Joanna Briggs Institute (Peters et al., 2015), will focus on interventions based on the Chronic Care Model or its individual elements to improve CKD care by primary care providers. For this review, "primary care provider" is defined as a physician (or trainee), nurse practitioner, or physician assistant providing direct patient care in ambulatory primary care settings. "CKD care" for this review focuses on screening, diagnosing, and/or managing patients with stage 1-4 CKD within primary care settings.

A scoping review approach was chosen because it involves flexibility in the types of articles that can be included and allows for a narrative analysis of a wide range of outcome measures within the selected framework. In this article, the Chronic Care Model and each of its elements will be introduced. Next, the question guiding this scoping review will be presented, as

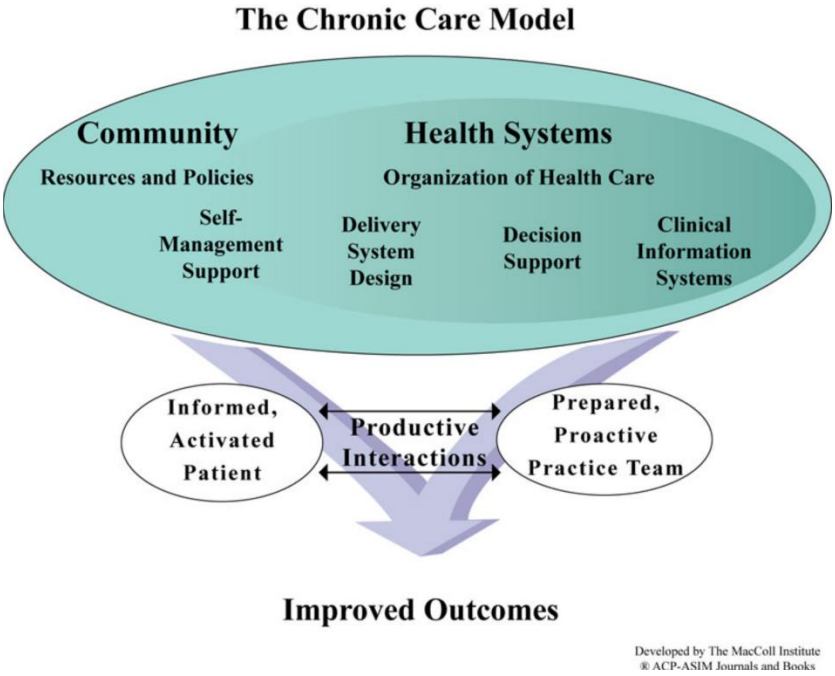
well as the inclusion criteria for the articles reviewed. Subsequently, the search strategy, the exclusion criteria, and a narrative description of the flowchart will be described. As is common with scoping reviews, the quality of each study did not impact its inclusion in this review (Peters et al., 2015), and both research and quality improvement studies were included as were both qualitative and quantitative studies. Then, the process for charting the results, also known as data extraction, included a table of the selected studies. Scoping reviews do not necessarily include a results section, but rather a discussion of the results noting the strengths and limitations identified. The discussion section in this paper will focus on providing a narrative overview of the evidence followed by implications for future research, quality improvement projects, and clinical practice.

The Chronic Care Model

The Chronic Care Model was established by the MacColl Center for Health Care Innovation and first reported in 1998 (Wagner, 1998) and updated in 2003 (MacColl Center for Health Care Innovation, 2006-2016). It is a multi-level framework for improving patient outcomes in those with chronic diseases. This framework has been applied to the management of a variety of chronic diseases and interventions, and it provides a wholistic organizational approach to identifying facilitators of better outcomes for individuals with chronic diseases. The Chronic Care Model (Figure 1) involves proactive planning at the community and health system levels so that patients and providers can have more productive encounters despite forced time constraints during primary care visits. The Chronic Care Model includes six elements that support productive interactions between patients and providers (MacColl Center for Health Care Innovation, 2006-2016): *community resources*, *self-management support* (SMS), *organization of healthcare* (OHC), *delivery system design* (DSD), *decision support* (CDS), and *computer*

information systems (CIS). It is important to note that these elements often overlap when they are operationalized, building on the integrative approach of the model. The Chronic Care Model is also designed to have all elements activated simultaneously to achieve the best patient outcomes.

Figure 1. The Chronic Care Model (MacColl Center for Health Care Innovation, 2006-2016)



The first element, *community resources*, includes non-profit, governmental, or faith-based organizations, research, and advocacy for policies that improve patient outcomes. This element can be operationalized as funding sources, program development, pragmatic trials, clinical practice guideline translation, and national initiatives such as Healthy People 2020 or Meaningful Use criteria for electronic health records.

Within the *self-management support* element, patients serve a central role in health management, and a collaborative approach including goal setting and action planning is advised. Interventions targeting this element typically involve individualized care planning and culturally tailored education about lifestyle, diet, and disease management. Organizationally, internal and

external resources for self-management can be compiled and made available. These interventions are meant to occur outside of the scheduled primary care provider visit.

The *organization of healthcare* element addresses the organizational mechanisms and culture that are in place. Operationalizing this element includes senior leadership or key stakeholder support for initiatives, system change strategies, internal incentives for quality of care, and agreements across organizations.

In the next element, *delivery system design*, roles of the various health care team members are defined and tasks are distributed. Regularly scheduled, planned interactions that support evidence-based care and that fit with the cultural background of the patient are also included in this element. Interventions that support delivery system design include cluster or team-based visits, using health volunteer workers, re-defining what role can manage certain aspects of care such as pharmacists adjusting medication dose or nurses adding diagnoses into the patients' records.

Decision support, often called clinical decision support, is an element that marries the most current scientific data with patient preferences. Evidence-based guidelines take a central role in this element, encouraging access to guidelines, continued education, embedding guidelines into standard practice, and sharing the evidence-based guidelines with patients. These interventions may be low-tech such as clinical pathway diagrams printed for use in an office, or hi-tech like automated ordering of tests in an electronic medical record (EMR) with options for provider override. Education is the most common use of decision support.

The final element, *clinical information systems*, focuses on the organization of data. This element includes timely feedback and reminders for providers and patients, identifying relevant sub-populations within the organization to facilitate individualized patient care planning, sharing

information with patients through coordinated care, and monitoring performance quality of the practice team and the health care system. This element can be operationalized through patient portals to electronic records, interoperability, disease specific registries as examples. The authors of the CCM posited that when all six elements are represented within an organization, a productive interaction between the patient with a chronic illness and the health care team will lead to improved patient outcomes (MacColl Center for Health Care Innovation, 2006-2016).

The Scoping Review Question

The question guiding this scoping review was, "How has the Chronic Care Model or its elements been applied in interventions for CKD identification or management in primary care settings, and to what degree of success?". The inclusion criteria were intervention or sustainability studies using one or more element described in the Chronic Care Model published in the English language as journal articles between 2008 and March 2018 involving human subjects. Additionally, CKD stages 1-4 must be either the focus of the study or a secondary screening outcome, articles reporting process measures or clinical outcomes were included. Exclusion criteria are discussed in the search strategy.

Methods

Search Strategy

The initial search was conducted in March 12- April 1, 2018 using PubMed, CINAHL, EMBASE, PsycINFO in that order, limiting to sources with abstracts available. Each site was searched for "Chronic Care Model" AND kidney (or renal) disease, chronic kidney (or renal) disease AND decision support, chronic kidney (or renal) disease AND delivery system design, chronic kidney (or renal) disease AND clinical information systems, chronic kidney (or renal) disease AND self-management support, chronic kidney (or renal) disease AND organization of

healthcare, chronic kidney (or renal) disease AND organizational structure, and chronic kidney (or renal) disease AND community resources. The Cochrane Database was also queried for initial review of abstracts and titles. Duplicates were removed with each new set of search terms and from each new database, using reference management software. A research librarian was consulted about search terms and databases. A flow diagram of abstract selection is presented in Figure 2.

Figure 2. Study flow, number of records at each iteration of inclusion/exclusion decision

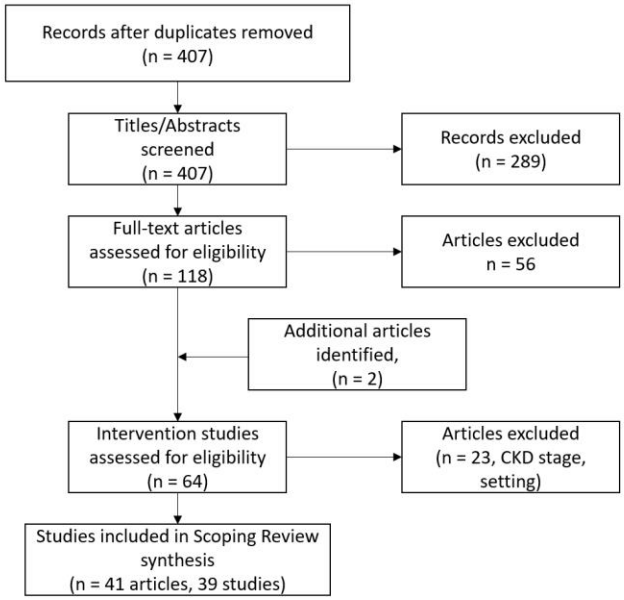


Figure 2. Study flow, number of records at each iteration of inclusion/exclusion decision

A total of 407 unique abstracts were included for initial evaluation. Due to the broad search terms used, many abstracts were retrieved but did not meet inclusion criteria. The review of abstracts retrieved during the preliminary search steps facilitated the identification of exclusion criteria. Exclusion criteria included 1) no intervention results (i.e., abstracts reported protocols, pathways, programs, reports, recommendations, prevalence); 2) findings stemmed from conference or review article (e.g., systematic, meta-analyses); 3) focused on end-stage kidney disease (CKD 5, dialysis, transplant, renal replacement therapy decision-making,

prognostic models) or another chronic disease without assessment of kidney function, acute kidney injury, 4) occurred in acute or long-term care, or nephrology specialty care settings, 5) included cost-effectiveness analysis only, 6) involved pediatric patient population; or 7) reported on a medication study focused on nephrotoxic side effects in a non-CKD population rather than renal dosing. After reviewing full text articles for exclusion criteria and adding two additional articles including secondary analysis of included intervention studies, the review includes 41 articles representing 39 unique studies. A single reviewer conducted the review of abstracts and this scoping review.

Charting the Results

The process of extracting and tabulating data from the published studies was also iterative. Categories of study components were established a priori to include author names, year published, country where intervention conducted, and outcome measures and results. Outcome information for each study was outlined into multiple distinct but not mutually exclusive categories: process or clinical outcome; provider workflow; involvement of nurses in the intervention, involvement of a nephrologist in the intervention; focus on CKD screening, management by a provider, or self-management (SMS); renal medication adjustments; or a focus on diabetes. A short synopsis of the results and discussion were also included. The outcomes for these selected articles are presented in Table 1. The connection of each study to the Chronic Care Model is presented in the discussion section.

Process outcomes focused on use of the intervention, provider feedback on the intervention, appropriateness of overrides of the intervention, or provider based outcomes such as ordering practices. Clinical outcomes focused on patient-specific biometric findings such as blood pressure or laboratory findings or self-management indices. This was not a mutually

exclusive category. The ways in which the intervention impacted provider workflow was expressed in three mutually-exclusive terms: (1) “External to work flow” indicated the intervention was outside of the providers’ usual activities such as accessing an outside resource or choosing to open a new order set in the EMR. (2) “Internal to workflow” indicated the intervention was integrated with normal workflow patterns of the providers such as decision support that automatically alerted the provider to a needed change. (3) “Non-provider” interventions were not limited to regularly scheduled primary care provider visits but were often carried out by other healthcare team members (e.g., pharmacist, nurse, or nephrologist). Nurse involvement indicated a nurse was engaged in receiving or administering the intervention. Involvement of nephrology indicated a nephrologist functioned in the delivery of the intervention and was not a recipient of the intervention or the study researcher. Diabetes-focused articles were those in which all patients had a diabetes diagnosis, but the study included a nephropathy or CKD component.

Four main outcome categories were separated out. CKD *screening* indicated that at least one focus of the intervention was on screening for CKD, while CKD *management* focused on CKD treatment indicators and outcomes from either the provider or patient management. Renal medication adjustments indicated studies that sought to reduce medication errors (dosages or inappropriate medication use) for patients with renal impairment. Finally, the results category referred to some mention of statistical significance or clinical significance, along with any relevant information from the article’s discussion section.

Table 1.

	Author	Country	Outcome	Workflow	Nurse Involved	Nephrology	Diabetes Focused	CKD Screen	CKD Manage (Prov)	CKD Manage (patient)	Renal adjust meds	Results
1	Abdel-Kader, K.,	US	C	External					*			NSD, possibly due to passive decision support

	Author	Country	Outcome	Workflow	Nurse Involved	Nephrology	Diabetes Focused	CKD Screen	CKD Manage (Prov)	CKD Manage (patient)	Renal adjust meds	Results
	et al, 2011											
2	Armstrong, N., et al., 2016	UK	P	No provider	*				*			many barriers to implementing a CKD program including competing priorities
3	Awdishu, L., et al., 2016	US	P	Internal							*	* ↑ use in some alerts (on prospective orders) but still low uptake
4	Barahimi, H., et al., 2017	Iran	C	No provider						*		*↓ in eGFR decline, but patients did not want to use the electronic system for SMS
5	Barrett, B. J., et al., 2011	Canada	C	No provider	*				*			NSD, nurse not offered nephrology driven protocols, only within scope of usual primary care practice
6	Bhardwaja, B., et al., 2011	US	P	No provider							*	* ↓ renal dosing medication errors, overall 20% sustained errors reduced
7	Blakeman, T., et al., 2014	UK	C	No provider						*		↑ BP control, HRQOL and self-management, low use of website resources
8	Cho, I., et al., 2014	US	P	Internal							*	renal warning medication overrides only appropriate 30% of the time, same providers and medications often the resulted in the low rate
9	Conway, N., et al., 2018	Scotland	P/C	Internal			*	*				↑ likelihood of screening for CKD, but concern over alert fatigue
10	Dickinson, L. M., et al., 2014	US	P/C	External			*	*				one size does not fit all in quality improvement models
11	Donald, M., et al., 2016	Canada	P	External				*	*			site was useful, but being that it was external to EMR, changed workflow and unable to directly refer patients
12	Drawz, P.E., et al., 2012	US	P /C	External					*			↑ PTH screening in both groups after providers educated, intervention group only used CKD registry 5 times

	Author	Country	Outcome	Workflow	Nurse Involved	Nephrology	Diabetes Focused	CKD Screen	CKD Manage (Prov)	CKD Manage (patient)	Renal adjust meds	Results
13	Ennis, J., et al., 2015	US	P	Internal				*	*			Testing of common labs (eGFR in chemistry and HCT in CBC) at 50%, but CKD specific screening (PTH, Vit D, TSAT, LDL, and UACR) remained low, statistically but not clinically significant
14	Harvey, G., et al, 2015 Humphreys, et al, 2012	UK	P/C	External	*			*	*			↑ addition of patients to CKD registry and blood pressure control, but lack of knowledge about use of registry and low priority of CKD in organization
15	Havas, K., et al., 2017	Australia	C	No Provider	*					*		↑ in self-management abilities, patients identified conflicting information from healthcare providers
16	Jiamjariyapon, T., et al., 2017	Thailand	C	No Provider	*				*	*		* ↓ in eGFR decline and improvement in renal dosing medications after self-management support team and home visits
17	Jolly, S. E., et al., 2014	US	P	External				*	*			↓ acknowledgement of CKD in EMR, if CKD identified, better CKD management
18	Karunaratne, K., et al., 2013	UK	C	No Provider					*			↑ BP control in patients with CKD 3-5 after a pay for performance driven program, sustained at least 2 years
19	Katz, I., et al., 2009	S. Africa	P	No Provider	*			*	*			Primary health nurses were able to accurately identify patients for nephrology referral, but referral process flawed, nurses were overworked and undervalued
20	Lee, B., et al., 2012	US	P	No Provider		population based neph			*			less severe CKD progression, more Cr levels ordered, and screening for nephrology referrals within primary care chart by nephrologist

	Author	Country	Outcome	Workflow	Nurse Involved	Nephrology	Diabetes Focused	CKD Screen	CKD Manage (Prov)	CKD Manage (patient)	Renal adjust meds	Results
21	Litvin, C. B., et al., 2016	US	P/C	External				*	*			significant ↑ in UACR testing, but not on other metrics, provider discrepancies between recommendations and clinical judgement, competing orders with a nephrologist, concerns about over diagnosis of CKD, additional steps to use tool, low use of registry
22	MacLean, C. D., et al., 2013	US	P	Internal			*	*				incorrect lab test for UACR was either ordered by the PCP or resulted by the lab, after correcting this, 20% increase in UACR ordering
23	Mark, D. A., et al., 2011	N. Ireland	P	No Provider		e-consult			*			virtual nephrology visits accounted for 23% of nephrology visits at end of study, decreasing the burden of traditional clinic visits, feedback was given to providers for patients who did not nephrology yet
24	Narva, A. S., et al., 2017	US	P	No Provider	*	e-consult	*		*			200 patients had nephrology access and slowed disease progression when seen in RN driven clinic with multidisciplinary team and tele-neph visits
25	Narva, A. S., et al., 2010	US	C	No Provider			*		*			↑ BP medications ordered, ↑ ACE/ARB use in diabetic hypertensive patients and microalbumin, ↑ BP control after IHS Chronic Care Model initiative
26	Pang, J., et al., 2016	Canada	P	External		mentor			*			PCPs reported ↑ knowledge of CKD and comfort providing CKD care, and ↑ access to nephrology for consul in a mentorship program. 76% of PCPs contacted their mentor.

	Author	Country	Outcome	Workflow	Nurse Involved	Nephrology	Diabetes Focused	CKD Screen	CKD Manage (Prov)	CKD Manage (patient)	Renal adjust meds	Results
27	Pefanis, A., et al., 2016	Australia	P/C	Internal	*			*	*			↑ UACR testing drove * improvements in CKD documentation, testing at-risk patients, and * reaching target goals in BP, HbA1c, and LDL after using an EMR tool, and CKD nurse support, however overall ordering remained low
28	Regan, M., 2017	US	P	External				*				* ↑ in CKD staging, UACR orders for CKD patients, and referral to nephrology based on eGFR or UACR occurred after a nurse conducted educational program and CDS pathway, PCPs showed an increased knowledge on post-test
29	Scherpbier-de Haan, N. D., et al., 2013	Netherlands	P/C	No Provider	*	mentor			*			* ↑ SBP control, PTH goals levels, and use of medications (lipid lowering and Vit D) in the intervention group after a nephrology led and NP delivered CKD management intervention
30	Shemeikka, T., et al., 2015	Sweden	P	External							*	Providers appreciated having eGFR posted on medication list section of EMR and noted a + awareness of renal function, however they questioned eGFR calculation. There were no dose adjustment recommendations embedded, required a link to external sites for guidance.

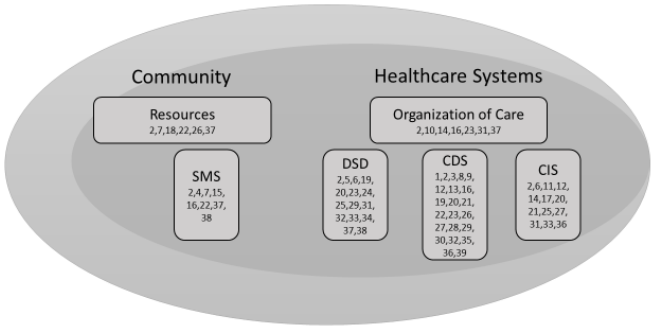
	Author	Country	Outcome	Workflow	Nurse Involved	Nephrology	Diabetes Focused	CKD Screen	CKD Manage (Prov)	CKD Manage (patient)	Renal adjust meds	Results
31	Sim, J. J., et al., 2015	US	P	No Provider	*			*				The SureNet program is managed by nurses and focuses on repeat lab testing for patients with an abnormal eGFR, first review of the program showed 51.8% retesting, 52.5% of those had CKD verified, but only 41.9% of those had it documented in EMR.
32	Sim, L. L., et al., 2017	Singapore	P	External			*	*				Med students who used the Diabetes dashboard versus usual lab report noted ↑ ability to identify CKD and outdated lab results, but not able to identify which patients needed change in management
33	Smith, Z. G., et al., 2016	US	P	No Provider	*	e-consult			*			216 patients reached co-management PCP/neph after identifying patients at risk and using a nephrology nurse screening process for e-consult or full visit recommendations
34	Tan, J., et al., 2015	New Zealand	C	No Provider	*					*		intervention group participants had lower BPs, decreased urine protein excretion, improved EKG readings after education sessions and ethnic-concordant healthcare assistants under nurse guidance, but these results did not sustain after return to usual care
35	Thomas, B., 2011	US	P	External	*			*	*			* ↑ in CKD screening and diagnosis, but diagnosis recording remained low at 32% after a nurse led intervention on EMR enhancements with provider scorecard feedback. There

	Author	Country	Outcome	Workflow	Nurse Involved	Nephrology	Diabetes Focused	CKD Screen	CKD Manage (Prov)	CKD Manage (patient)	Renal adjust meds	Results
												was low use of the enhancements (4%).
36	Toh, M. P. H. S., et al., 2009	Singapore	P/C	Internal			*	*				Nephropathy screening in diabetic patients did not significantly improve after adoption of a Chronic Disease Management system
37	Tracey, K., et al., 2013	Australia	P	No Provider	*	coordinated visits		*	*			A nurse led clinic was designed to bridge the gap in nephrology access for remote patients and succeeded in decreasing long trips for consult, ↑ identification of ESRD, decreased hospitalizations, increased local access to nephrology visits and vascular access
38	Walker, R. C., et al., 2013, 2014	New Zealand	C	No Provider	*					*		* ↓in UACR but also eGFR, * ↓ in BP, cholesterol, A1C, reported smoking, and ↑ in self-management scores occurred after a nephrology NP SMS intervention
39	Wentworth, A. L., et al., 2011	US	P	External				*	*			Initial findings from CDS, reminders, academic detailing, and feedback intervention * ↑ in anemia management, evaluation PTH, phosphorus, Vit D, and referrals to nephrology, but 2-year follow-up showed these levels were not sustained, but remained higher than baseline

Discussion of the Results

A majority of these articles were published after 2012 (n = 29) and involved studies conducted in the United States (n = 15), a complete list is provided in Table 1. There was a variety of journals represented with most articles appearing in nephrology (n = 16) or primary care (n = 10) journals. Each of the Chronic Care Model elements were represented by at least one intervention, but only one study noted use of all of the elements (Armstrong, Herbert, & Brewster, 2016). Figure 3 illustrates the studies' application of the elements. The most commonly used element was *decision support* (n = 22), followed by *delivery system design* (n = 15) and *clinical information systems* (n = 13). There was often overlap of decision support and clinical information systems as Meaningful use for electronic health records and the focus on health informatics continues to grow. There were interventions, however, where educational sessions alone positively impacted outcomes regardless of electronic decision support tools. *Self-management support* (n = 8), *organization of healthcare* (n = 7) in seven, and *community* (n = 6) were applied less often. It is important to note that many articles were excluded because although they described programs for CKD management, no results were reported within years included in this review. Studies with interventions that applied more elements of the model were better able to identify systemic barriers to CKD identification but were less able to determine which element contributed the most to any noted improvement.

Figure 3. Illustration of application of Chronic Care Model elements using study numbers listed in Table 1.



Key: SMS = self-management support, DSD = delivery system design, CDS = clinical decision support, CIS = clinical information systems

Process outcomes were the most common type of outcome measured (n = 22) followed by clinical alone (n = 9), and both process and clinical (n = 8), The process outcomes often included both ordering or diagnostic behaviors, but also perspectives on the usefulness of the intervention. When intervention tools were external to typical workflow (n = 13), such as patient registries, web links external to the EMR, passive alerts that required additional steps to fully activate, or reports that were different, providers were less likely to access or use the tool. When interventions took into account typical workflow and created tools that were incorporated into workflow (n = 7), outcomes improved; however, without input from the providers or a solid knowledge on CKD guidelines, within the tool, providers did not use these tools to their full effect either. Some providers noted a conflict between their clinical judgment or knowledge and what the tool was recommending. Interventions in which the primary care provider was not the focus more often had significant improvement in measured outcomes. That success could be because these interventions offered an adjunct to usual care and did not occur under the same time restrictions as a primary care visit.

Nurses with roles in the intervention were identified in 15 studies. However, many of the journals did not include licensure of the authors, therefore it is possible that nurses were involved in more of these studies than is noted here. Nurses were used in a variety of ways – from training

to screening, delivering SMS or CKD management interventions, and leading specialty clinics. In some interventions, it was noted that nurses were not given full authority to follow protocols or to use protocols that offered more CKD-specific care. The power dynamic between nurses and physicians was also noted in studies where nurses were given intervention protocols or were employed by the physicians in a general practice. Nephrology nurses, specifically, were included as educators and resources for both primary care staff members and patients. Nephrologists were delivering parts of the intervention in seven of these studies. These nephrologists provided education, mentorship, and/or consultation to primary care providers. In fact, PCP consultation with the nephrologist often resulted in increased confidence for the PCPs and a decrease in inappropriate patient referrals to nephrology, in terms of patients at earlier CKD stages who could be managed well in primary care settings. There were four studies specifically focused on patients with diabetes.

CKD screening outcomes reported in studies (n = 17) included diabetic nephropathy testing by estimated glomerular filtration rate (eGFR) or urine albumin: creatinine ratio (UACR), as well as this same testing in other high-risk populations such as patients with hypertension. In these CKD screening interventions there was a focus on increasing PCPs' understanding of the utility of both eGFR and UACR tests in identifying and staging CKD. Also, while CKD screening rates improved in most studies, often with statistically significant changes, CKD management for providers was the most common of the outcomes (n = 23) and was often accompanied by CKD screening outcomes and interventions including a nephrology specialist component. In one study, a nephrology nurse acted as an intermediary manager to determine a patient's need for a nephrology consult (Smith et al., 2016b). CKD management included lab testing, prescribing, or nephrology referrals for patients with documented CKD. CKD

management via self-management support used both biometric and/or self-management outcome measures such as ability to recognize and manage symptoms to determine the clinical relationship. The patients were more likely to engage in the self-management interventions when the intervention was delivered by a person, rather than via accessing an online system. Several articles indicated that great care was taken to ensure culturally appropriate self-management support resources for Native/Aboriginal patients who were at highest risk. Renal medication adjustment studies (n = 4) were pharmacy-alert focused, but only one study used pharmacists to carry out the intervention (Bhardwaja et al., 2011). Most of these renal adjustment interventions reduced the number of incorrect medications ordered or wrong dosage orders for individuals with impaired renal function; however, those improvements did not meet the intended success rates established for the intervention.

Most authors pointed out when a statistically significant finding was not necessarily clinically significant in order to no over-represent of the utility of the intervention. Also, many authors offered reflections on ways to improve these outcomes in the future. Often-cited barriers included lack of prioritization of CKD in primary care settings, lack of knowledge/confidence in CKD guideline-based screening and management, alert fatigue for embedded decision support, and financial restrictions. In interviews with healthcare team members across studies, delivery system re-design was often cited as an element that might be most useful. Examples of such design changes included using nurses to their full potential and creating multidisciplinary teams with clear roles to lessen PCP burden during patient visits. System redesign was also noted as a barrier because system change can be very difficult to achieve. The use of health volunteers for SMS proved effective, but not sustainable once those programs ended.

This scoping review has a few limitations that must be noted. One reviewer carried out the search and determination of articles as well as the analysis, which may introduce bias into the review. Additionally, because a scoping review approach was used, the quality of the articles was not assessed prior to inclusion.

Implications

Nurses were shown to have a positive impact on interventions, particularly nurses with CKD knowledge. CKD nurses, both registered nurses and advanced practice nurses, then, have the opportunity to positively impact CKD screening and management, primarily because of the specialized knowledge they possess. This knowledge includes staging progression of CKD and management of related complications such as anemia and altered mineral metabolism. This scoping review identified the benefit of sharing that specialized knowledge with staff in primary care settings, both for providers and patients who have not yet been seen in nephrology clinics. In addition, there is decreased burden on nephrology clinics to provide care to patients who could be managed in primary care settings. Partnerships, shared-care, or coordinated care models addressing the issue of CKD screening and management would all benefit from CKD nurse involvement, especially in areas where nephrology care is limited.

Conclusions

This scoping review aimed to highlight how the elements of the Chronic Care model have been applied to primary care screening and management for CKD and to what degree of success. The most successful interventions did not put all of the onus on the primary care provider changing practice behaviors, instead they focused on a systems approach to care delivery. That successful systems approach most often involved re-designing roles and bringing in adjunct team members with specialty knowledge or integrating interventions into existing workflows. For

patient-based interventions, personal delivery of education and support was more effective than web-based interventions, regardless of education level of person delivering the intervention (nurse practitioner, nephrology nurse, primary care nurse, or trained community health worker). In conclusion, while there is still room for improvement in screening and managing CKD in primary care settings, the literature reviewed shows promise and a move in the right direction.

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Chapter 6

Screening for Chronic Kidney Disease in a Hypertensive Primary Care Cohort: A Case Study.

Low screening rates for chronic kidney disease (CKD) in high-risk populations is well documented in the literature. Primary care providers are well positioned to screen high-risk patients, but many barriers have been documented including low awareness of evidence-based screening recommendations, low confidence to diagnose or stage CKD, and uncertainty about which patients need screening and which laboratory tests are most effective for diagnosis. Early identification of CKD has become the focus of national programs such as the Center for Disease Control's CKD Initiative and the Healthy People 2020 CKD Objective. The Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group (2012) guidelines focused on translating the best available evidence-based recommendations into practice and recommended two markers for CKD screening and staging: estimated glomerular filtration rate (eGFR) and urine albumin: creatinine ratio (UACR). While automated eGFR reporting, as part of chemistry panels, has helped somewhat to improve recognition of that marker of nephropathy, UACR testing and interpretation remains low. UACR results have also been shown to be critical markers of kidney function in certain sub-populations of higher risk, including African Americans and patients with hypertension, as eGFR may remain stable even in the presence of albuminuria. Whether knowledge of the guideline recommendations alone increases CKD screening, or if there are other contextual or patient specific factors, such as organizational support or insurance status, that may influence a provider's decision to order screening tests has yet to been determined. The purpose of this exploratory case study was to delve further into the

practices and contextual factors that are related to primary care CKD screening in a cohort of young men with hypertension within one academic medical center organization.

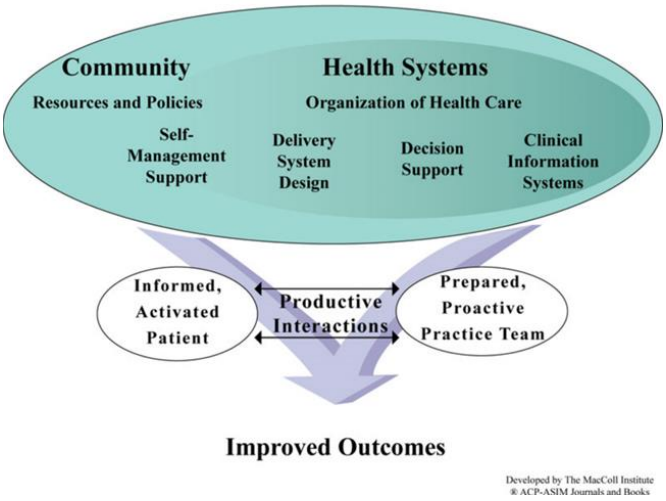
Methods

This observational mixed-methods study has an embedded single organizational case study based on the methodology described by Yin (2014) and utilizes a convergent parallel design, as presented by Creswell and Plano-Clark (2011), where all data is collected simultaneously and therefore results from one type of data does not inform collection of another data type. Case studies in medical literature often focus on a single patient and present a variety of details that help piece together a complex medical phenomenon. Similarly, this exploratory case study report, based on a single organization, uses a new approach to present the results of studying a variety of data types and variables that, when integrated into the final case creation, may more fully describe CKD screening in primary care settings.

The case for this study is defined as one academic medical center organization with five embedded primary care clinics and includes the providers who place orders, the patients who received care from these providers, and the resources available to providers for best clinical practice. The convergent parallel design allowed for convergence of the results to present one case description. The Chronic Care Model (MacColl Center for Health Care Innovation, 2006-2016) forms the framework for this study (Figure 1). Specifically, five of the model elements (community resources, organization of healthcare, delivery system design, decision support, and clinical information systems) were chosen as the predicted patterns to be used in pattern matching analysis to explore the screening rates for CKD present in the patient cohort. Results from a scoping review of the literature that applied this model to CKD screening and management in primary care settings (See Chapter 5) helped identify the types and sources of

data collected for this study. The University of Washington Human Subjects Division determined that the study was exempt from Institutional Review Board review.

Figure 1. The Chronic Care Model



Data Collection

Data was synthesized from review of organizational clinical decision support, medical records, and a provider survey from five purposively chosen primary care clinics within one academic medical center organization in the Pacific Northwest. These clinics were chosen because they have the highest rates of Medicare/Medicaid and charity care within the organization, and their patients' insurance status might impact laboratory test ordering. Additionally, two of these five clinics serve as acute management safety-net sites for low-income populations, many of which are without stable housing, whereas the remaining three clinics are set-up more for chronic disease management, but also serve a population living with lower socioeconomic means. The heterogeneity of these clinics demonstrates some of the variation that exists within the organization for the final case analysis.

Organizational Decision Support. This type of data focused on the internal clinical decision support for guideline translation that would be available to primary care providers during a patient visit. Because this organization does create specific policies or procedures for

these conditions, a review was conducted of available external resources on guidelines. All clinics included in the study have the same access to resources. The researcher met with a primary care provider in the organization and together they accessed the electronic medical record (EMR), which was determined to be the source of resources used during a visit. No patient information was shared with the researcher. The provider demonstrated use of the EMR and how the resources would be accessible to a provider during a patient visit. The types of available external resources with embedded hyperlinks were recorded. Additionally, in follow-up communications, the provider was asked whether the EMR includes decision support for hypertension, such as suggestions for laboratory testing, medication choices, or a clinical pathway for reviewing laboratory results.

Medical Records. The second type of data, EMR, was collected and deidentified by the Institute of Translational Health Sciences specifically for this study in February of 2018. The records were limited to primary care visits that occurred during calendar year 2016 in the five specified clinics. These visits were with African American (AA) and European American (EA) male patients ages 18-44 years with hypertension recorded in the problem list and no other co-morbid conditions. This age range and diagnosis were chosen because lower blood pressure control has been found in younger patients with hypertension, aged 20-39, in men, and in AA compared to EA patients (Guo, He, Zhang, & Walton, 2012), thus increasing CKD risk. Two different ethnic categories were used as a comparison because AAs with hypertension may be more likely to present with microalbuminuria before a decrease in eGFR levels (Dasmahapatra et al., 2011) and are at higher risk for development of end stage renal disease than their EA counterparts, but are a smaller sub-population of patients seen in this area of the Pacific Northwest. This higher risk may not be as well known amongst primary care providers. The

initial goal for patient record sampling was 100 patients (50 AA, 50 EA) per clinic, however it was anticipated that the inclusion criteria might limit the actual number of patient records available for analysis. The variables included in the record review were age; type of insurance; clinic visited; blood pressure reading; encounter with the patient's documented primary care provider during the visit; laboratory tests ordered for metabolic panels (which include the eGFR), urinalysis (UA), and/or UACR; documentation of incomplete tests; laboratory results; and the number of different antihypertensive medication prescribed. The eGFR test results were reported as both AA and non-AA levels, and the appropriate result for each patient was included in analysis.

Survey. The third data type, a provider survey, was collected and managed using REDCap electronic data capture tools hosted at the University of Washington (Harris et al., 2009). Previously used questions from three published articles (Abdel-Kader, Greer, Boulware, & Unruh, 2014; Agrawal, Ghosh, Barnes, & McCullough, 2008; Flottorp et al., 2013) served as the basis for most of the questions in this survey. These three sources were chosen based on their content relevant to CKD or guideline implementation, previous use in published literature, and applicability to the Chronic Care Model framework as it is applied in this study. The provider survey (Appendix A) consisted of a presentation of a hypothetical patient followed by questions asking about laboratory order preferences and utility, CKD risk factor identification, CKD or hypertension guideline awareness and utility, preferences for increasing one's own CKD knowledge, CKD as a priority within the organization, and the provider's demographic characteristics. An additional optional section of the survey included both open- and close-ended questions that focused on provider preferences for practice guideline uptake resources,

organizational capacity to meet those preferred resources, and the factors that most influenced the use of the guideline-based recommendations.

The accessible population for the survey consisted of all primary care providers who work in any of the five designated primary care clinics. Primary care providers within this organization are defined as physicians, nurse practitioners, physician assistants, and resident physicians (who see patients under an attending physician's supervision). The target population for this study is all providers who are responsible for assessing patients and ordering labs during primary care visits. Medical directors from each of the clinics agreed to contact the providers for participation via email. An email was sent to providers through their organizational email address in February and March of 2018 with the survey remaining open until March 31, 2018. The email contained an introduction to the study from the lead researcher and the REDCap hyperlink to the survey. One reminder email was sent to two of the clinics, and one clinic medical director invited a guest presenter to introduce the survey in a staff meeting. The REDCap system was not set up to obtain any identifying information therefore, the survey was anonymous. A total of 125 providers were invited to complete the survey (excluding the provider contacted for the first data type).

Analysis

Organizational Decision Support. External resources available via hyperlink in the EMR, the description of EMR decision support for hypertension management, and the pathway of laboratory result review were documented through field notes and stored electronic communications. These data were used for pattern matching in the case creation analysis and were not analyzed separately. Pattern matching across data sources, as described by Yin (2014), helps strengthen the internal validity of the study.

Medical Records. The deidentified data were received in three Microsoft® Excel spreadsheets and were cleaned and integrated using the same program. Encounters with other healthcare team members only such as nurse, social worker, medical assistant, nutritionist, or pain clinic (n = 181) and duplicate visits where the patient was seen by more than one provider such as a resident with attending oversight (n = 101) were excluded from analysis. The remaining 1458 encounters were consolidated so that each patient had one unique summary code (n = 394). For patients who had multiple encounters, the highest systolic blood pressure reading and number of blood pressure medications prescribed were recorded, and any record of charity care, primary care provider seen, or laboratory order entered by the provider were coded as present in the consolidated data point. IBM SPSS 19 was used to run descriptive statistics on patient demographics. After four patients were removed due to missing data, two multiple logistic regressions with simultaneous predictor entry were conducted to model metabolic test and UACR ordering in a sample of 390 patients. Clinic specific membership and provider seen were evaluated to determine if the regression model could focus on organizational-level variables and they did not significantly contribute to the metabolic testing or UACR testing ($p < 0.05$) and were therefore removed from the model. *A priori* covariates entered into the model included standardized age and standardized number of visits (Z-scores to establish an average patient encounter profile), blood pressure, number of medications, insurance, and whether patient saw his established primary care provider in any encounter during the year.

Survey. Descriptive statistics of quantitative survey data for all providers across clinics were completed using Microsoft Excel given the small sample size. Only questions that related to the organization or guideline uptake were included in this analysis. For the open-ended questions, inductive narrative categorical-content perspective analysis (Lieblich, Tuval-

Mashiach, & Zilber, 1998) was used identify codes for convergent or divergent findings. This type of analysis allows for interpretive coding of words and phrases into categories after open reading of subtext. Convergent findings were coded together, while divergent or outlier codes were established when only one provider wrote a specific answer. Providers were not limited to one code as they often offered multiple answers to the same question. Each of the open-ended questions also had a follow-up closed-ended question that was used for pattern matching between provider needs and organizational ability to support those needs.

Organizational Case Creation. Predicted patterns for comparison were based on the elements of the Chronic Care Model. Each of the model elements, except for *self-management support,* are represented in the sources and types of data collected. Pattern matching occurred within and between the different types of data and within the elements. The extent of testing for CKD in the patient cohort was the outcome of interest for the case. Analysis of the *community resource* element occurred by reviewing the types of external guideline-based resources accessible through the EMR and the use and awareness of guidelines or recommendations queried in the survey. The *organization of healthcare* was addressed in multiple survey questions, by identifying providers' level of agreement with CKD being a priority in the organization. The *delivery system design*, *decision support,* and *clinical information systems* elements were represented in data from the provider survey, including the optional questions, in descriptive statistic form.

Rigor

Yin (2014) describes case study tactics to address the four quality tests of a research study. Construct validity was addressed by using multiple sources of evidence to create the case and using the theoretical framework and established current literature on CKD to guide the

variables that were collected. Internal validity is more complicated to address in an observational case study; however, pattern matching across the variables during analysis was used because it is a tactic Yin recommends for addressing internal validity case study research. External validity for this case study was addressed in the design of the single-embedded case. The variability in clinic type with access to the same resources within the one organization may translate to other healthcare organizations with multiple primary care clinics. Reliability was addressed in multiple ways throughout the study. All of the variables chosen for collection were based on elements of the theoretical framework and the current literature in an attempt to manage bias in the case creation. The research protocols for the collection and analysis of the *medical records* and *survey* data types of the case study are easily replicable. The change in types of clinic resources included as well as the means for collecting that data were made transparent. Additionally, a chain of evidence as described by Yin (2014) was maintained. Field notes were maintained and copies of electronic communications saved for the *resource* data. *Medical record* data was saved and dated throughout data cleaning and the consolidation process. *Survey* data collection was managed through the REDCap system which allowed for tracking of dates and times of survey completion as well as the direct export of the data for analysis. Standard statistical analytic methods were used for the quantitative data. Additionally, the convergent parallel design established a priori led to a clear analysis plan for the pattern matching at the case level which was based on the theoretical framework.

Results

Organizational Decision Support. During the meeting with the designated primary care provider the EMR was opened and the resources link accessed. Resources that were most easily accessible from this link included Up-To-Date®, U.S. Preventive Services Task Force, and The

National Guideline Clearinghouse™. There were no direct hyperlinks in the EMR for disease-specific guidelines or organizations; however, those resources are available to clinicians through the library system, which includes a health sciences library and librarian. In follow-up emails with the primary care provider, EMR decision support was discussed to further clarify the accessibility of guideline-based resources and the process of identifying laboratory results that are out of normal limits. The EMR is able to offer a basic level of clinical decision support, such as the requirement for metabolic laboratory testing for patients on a diuretic, but did not offer recommendations for laboratory testing for other anti-hypertensive medications or for hypertensive patients in general, nor did the decision support offer a recommendation on how to apply the laboratory results to patient care. There was also not Laboratory results that are abnormal are flagged in the system and the registered nurse or medical assistant will notify the provider of this alert. However, the provider noted that this is the same flag alert is available to providers, and therefore they may react to results even before any notification by the nurse or medical assistant and no decision support accompanies the alert.

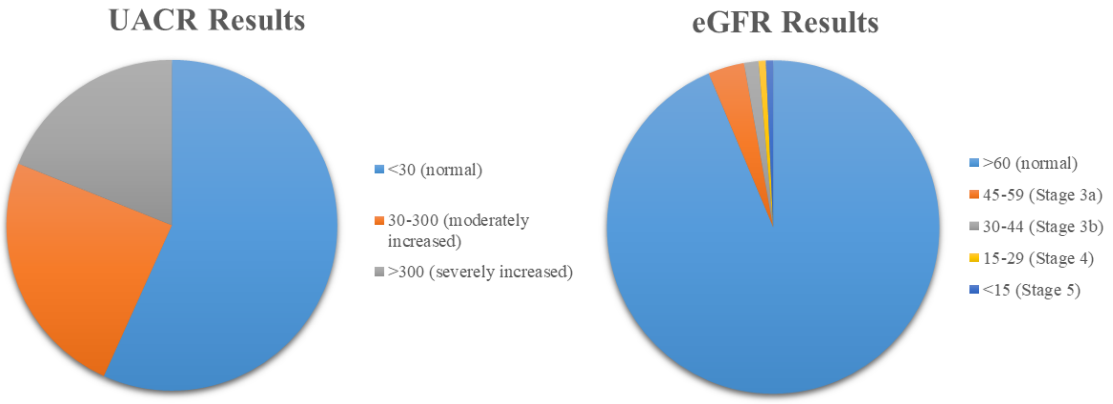
Medical Records. Table 1 presents clinic-level descriptive data on insurance type, race, and number of patients. The initial sample size goal was not reached in three out of the five clinics. Of the 394 patients, 145 were prescribed anti-hypertensive medications. The laboratory testing data showed that all 256 tests that were ordered were completed by the patients (eGFR n = 176 [69%], UACR n = 41 [16%], and urinalysis n = 39 [15%] of tests ordered). The urinalysis results were not analyzed for this sample due to lack of International Statistical Classification of Diseases and Related Health Problems (ICD) coding associated with the order, which made it difficult to determine the indication for the urinalysis (e.g., to rule out infection or monitor urine protein). Additionally, according the KDIGO guidelines, urinalysis is not the recommended test

for assessing urine protein for CKD diagnostics (KDIGO, 2013). Of the 394 total patients analyzed, lab results for metabolic panels were ordered 146 patients, but one test result was scanned and could not be viewed, and two tests were not completed due to sample error leaving 143 patients. UACR tests were ordered in only 37 patients. Of note, the highest possible eGFR results were >60 ml/min and those are considered normal levels in this organization. Simultaneous eGFR and UACR orders were recorded 23 times while 18 tests for UACR alone were recorded. Figure 2 illustrates the eGFR and UACR results in this case, based on KDIGO CKD staging (KDIGO, 2013). The lightest areas in the pie charts depict normal results and highlight a distinct difference in kidney function between the two testing methods on these patients. Results from the eGFR tests were normal in 89% of the cohort versus only 54% normal UACR results. For the patients who had simultaneous testing, ten had normal results for both tests, four had a "severely increased" UACR level with normal eGFR, five had a "moderately increased" UACR level with normal eGFR, two had stage 3b eGFR results with normal UACR, and two had abnormal levels on both UACR and eGFR.

Table 1.
Descriptives of Insurance and Race by Clinic

	Clinic 1		Clinic 2		Clinic 3		Clinic 4		Clinic 5		Totals	
	n = 101		*n = 101*		*n = 80*		*n =100*		*n = 12*		*n = 394*	
	N	*%*	*N*	*%*	*N*	*%*	*N*	*%*	*N*	*%*	*N*	*%*
Insurance Type												
Private	16	16%	14	14%	4	5%	60	60%	0	0%	94	24%
Medicare	3	3%	4	4%	2	3%	5	5%	1	8%	15	4%
Medicaid	67	66%	59	58%	62	77%	32	32%	9	75%	229	58%
Charity	14	14%	23	23%	11	14%	1	1%	2	17%	51	13%
Injury	0	0%	0	0%	0	0%	1	1%	0	0%	1	0%
Missing	1	1%	1	1%	1	1%	1	1%	0	0%	4	1%
Race												
African American	51	51%	50	49%	33	41%	17	17%	1	8%	152	39%
European American	50	49%	51	51%	47	59%	83	83%	11	92%	242	61%

Figure 2. eGFR and UACR results and KDIGO CKD Staging



Two logistic regressions were performed to identify patient encounter predictors of CKD screening test ordering for metabolic testing and UACR testing (Table 2). Based on guideline recommendations, all patients with hypertension should be screened for CKD annually. The first logistic regression focused on metabolic testing. A test of the model fit with all predictors added was statistically significant, the omnibus $X^2(7) = 69.41$, $p < 0.001$ in which a statistically significant result indicates the predictors help reliably distinguish between individuals who had the metabolic test ordered and those who did not. The model's Nagelkerke's pseudo-$R^2 = 0.22$, and sensitivity and specificity were 40% and 87%, respectively with 70% correctly classified. The predicted mean probability of ordering the metabolic test was 28%.

Age, insurance type, and whether or not the patient saw his primary care provider were not significant predictors of metabolic test ordering. However, race, number of visits, highest recorded systolic blood pressure (effect coded), and number of anti-hypertensive medications prescribed (effect coded) were significant contributors.

When looking at the predictive values calculated from the logistic regression on metabolic panel testing, an AA man of average age (36.87 years, SD = 6.22), average number of visits (3.75, SD = 4.49), with maximum systolic blood pressure less than 130, on no anti-hypertensive medications, with private insurance, and seeing his assigned primary care provider

has a 32% predicted probability to get a metabolic test ordered, whereas a EA male with the same predictors has a 19% predicted probability of getting a metabolic test ordered. When adding one or two anti-hypertensive medications to this equation, the predicted probability of CMP ordering increases to 52% for AA men and 36% for EA men. For men who do not take anti-hypertensive medications but do have a maximum SBP greater than 130, AA men had a 42% probability to have the CMP test ordered while EA men had a 27% probability. Among men who were seen more often, without elevated systolic blood pressure and were not taking anti-hypertensive medications, AA men with a one SD deviation increase in number of visits had a 41% predicted probability to have a CMP test ordered, while their EA counterparts had only a 26% probability.

Another multiple logistic regression with simultaneous entry was used to predict UACR test ordering with the same sample and N. Again, clinic membership and provider seen were not significant contributors to the outcome and were removed as predictors. A test of the model fit with all predictors was also significant, $X^2(7) = 18.81$, $p = 0.009$, indicating the predictors reliably distinguish between individuals with UACR tests ordered. However, with an even lower Nagelkerke's pseudo-$R^2 = 0.10$, these predictors did not explain well the probability of ordering lab tests, likely due to the even smaller number of tests ordered (n = 41). The percent correctly classified in this model was 91%. The predicted mean probability of ordering the UACR test was 4%. No predictors other than race were significant contributors to UACR testing. Using the same descriptors as above of age, visits, SBP, medication, insurance, and seeing PCP, an AA man has a 9% predicted probability of UACR order, whereas his EA counterpart only 4% probability.

Table 2.

Multiple Logistic Regression with Standard Predictor Entry Metabolic and UACR Test Ordering

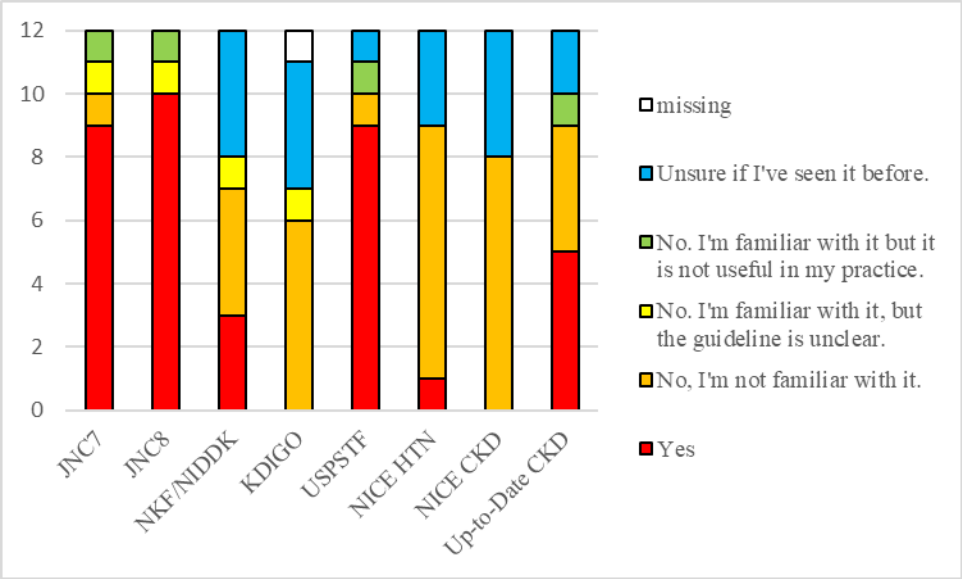
	$\chi^2(7)$	*p*	*Pseudo* R^2	*Sens*	*Spec*	*HR*	*b*	*(SE)*	*Wald* (1)	*p*
Metabolic Test	69.41	<0.001	0.22	0.40	0.87	0.70				
Intercept							-0.93	(0.31)	8.71	**0.003**
Standardized Age							0.13	(0.12)	1.15	0.284
Standardized Number of Visits							0.42	(0.13)	10.22	**0.001**
Max SBP							0.45	(0.23)	3.96	**0.047**
Number of Medications							-0.85	(0.21)	15.90	**<0.001**
Race (AA)							0.88	(0.24)	13.22	**<0.001**
Insurance							0.04	(0.20)	0.04	0.837
PCP seen							0.30	(0.28)	1.15	0.837
UACR Test	18.81	0.009	0.10	0.00	1.00	0.91				
Intercept							-3.09	(0.55)	31.84	**< 0.001**
Standardized Age							0.15	(0.20)	0.60	0.440
Standardized Number of Visits							0.22	(0.15)	2.30	0.129
Max Systolic Blood Pressure							0.45	(0.39)	1.35	0.245
Number of Medications							-0.33	(0.30)	1.26	0.261
Race (AA)							0.99	(0.37)	6.99	**0.008**
Insurance							-0.11	(0.32)	0.12	0.728
PCP seen							0.26	(0.47)	0.30	0.583

Note. N=390, sens = sensitivity, spec = specificity, HR = hit rate, SBP = systolic blood pressure, PCP = primary care provider

Survey. The 12 provider survey participants all identified as European American, gender identity was 50% each male and female, 67% were medical doctors or doctors of osteopathy, 75% worked full time and had more than 10 years of experience as providers with this organization, all had at least 5 years of experience as a provider, and they represented four of the five clinics. Of the survey respondents, 10 providers thought that CKD was "somewhat" or "to a great extent" a priority in the organization. Their familiarity with or use of CKD-specific guidelines or recommendations was low, while use of the Joint National Committee 7 and 8 recommendations for blood pressure management and the U.S. Preventive Services Task Force

recommendations was high. Figure 3 illustrates the familiarity and use of the selected guidelines or recommendations.

Figure 3. Reported Use and Familiarity with Guidelines



Note: N = 12 Provider responses, JNC = Joint National Committee, NKF = National Kidney Foundation, NIDDK = National Institute of Diabetes and Digestive and Kidney Diseases, KDIGO = Kidney Disease: Improving Global Outcomes, NICE = National Institute for Health and Care Excellence, HTN = Hypertension, CKD = Chronic Kidney Disease

The results of the optional questions showed a variety of responses that were narratively coded by content or meaning of the words and phrases used. Responses had both single and multiple codes assigned, which are presented in this section as a narrative result. Provider views on guidelines in general varied. While guidelines were seen as helpful resources in general, there was noted difficulty with their real-world application, especially when individualizing patient care. Some providers also questioned the quality of evidence that led to the guideline recommendations. Providers were also asked about feedback on their practice that they receive from the organization, and they mentioned a feedback mechanism that is built in to the EPIC EMR system as a quality results dashboard. However, some providers stated the dashboard only

contains a few quality markers and some were not sure what they were supposed to do with the dashboard feedback.

Providers were asked about four means of translating guidelines into practice: education-technology- human resources-monitoring/feedback, that they would find most helpful if the organization were adopting a new clinical practice guideline to increase identification of kidney disease. There was some overlap in responses regarding these organizational resources. Providers were open to receiving academic detailing about guidelines and new recommendations presented in regularly scheduled meetings or via email. Across all three of these resources, participants indicated they needed other staff to make uptake of the new guideline happen. They mentioned that nurses, medical assistants, coordinators, and nephrologists should have purposeful roles for contacting patients about testing, reviewing, and following up on laboratory results. One participant said, “currently PCPs do all of this and it’s overwhelming” while another said of access to nephrology review or consultation, “getting a patient in to our nephrology clinic is impossible!!”.

Organizational Case Creation. Laboratory screening for CKD, the patient-based outcome, was low in this cohort of hypertensive patients, despite the higher testing probability amongst higher-risk patients. Only 37% of the patients had a metabolic panel ordered, and 9% had testing for UACR. None of the patients in the cohort had CKD documented in the EMR problem list (thus meeting inclusion criteria); however, 23 patients met the KDIGO CKD prognosis of “moderate to very high-risk” criteria, though it is important to note that few patients had these results confirmed by repeat testing. Abnormal eGFR test results (n = 17) were reported for nine patients who met CKD staging 3b-5 criteria. Only four of those patients had

simultaneous UACR orders, with two having severely increased UACR levels. Of the remaining 14 patients with abnormal UACR results, six did not have simultaneous metabolic panel results.

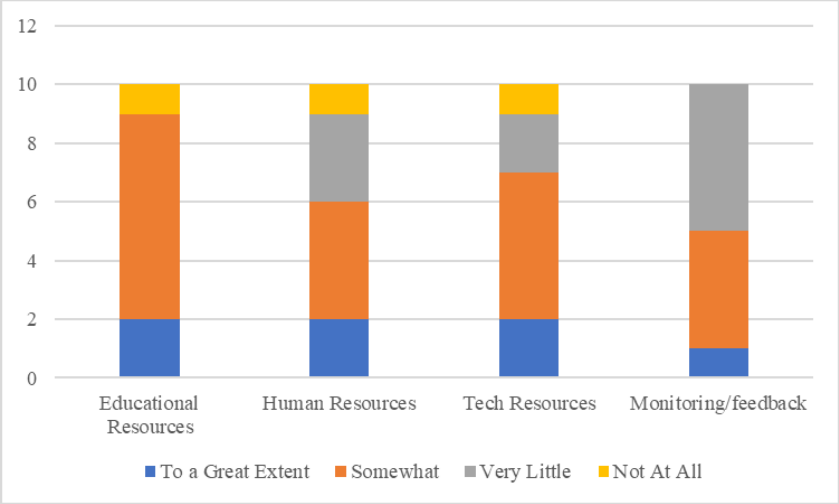
The guidelines themselves, which fall within the *community* element of the Chronic Care Model, play an important role in the case. While the guidelines used were external and developed outside of the organization, the providers' thoughts and described use of the guidelines are part of the case. The providers have access to external resources, but there is no specific translation of CKD screening guidelines within the organization, limiting *decision support*. Two external resources readily available from the EMR and included in the survey are the US Preventive Services Task Force Recommendations and Up-to-Date®. Survey participants were familiar with the US Preventive Services Task Force as a resource. The CKD screening recommendation from this task force (U.S. Preventive Services Task Force, 2012) states that population-based screening is not appropriate but provides an exception for individuals with diabetes or hypertension. These recommendations also include using both eGFR and UACR to diagnose CKD. Although the EMR offers a direct link to Up-to-Date®, survey participants were split on familiarity with the "Screening for CKD" (Obrador & Tonelli, 2016) section in this resource. Survey participants also reported using the Joint National Committee Recommendations on blood pressure management. While there is guidance on changing anti-hypertensive medications in the presence of proteinuria, one example of *clinical decision support*, there are not specific recommendations for when to order laboratory tests or the testing frequency (Chobanian et al., 2003; James et al., 2014). The CKD-specific guidelines were least likely to be marked as "used" due to lack of familiarity with the resources. Furthermore, survey participants were asked about motivators for ordering guideline-recommended tests. The participants did not agree that clinic-level reimbursement as a reason to order tests but instead

noted patient preferences as an important factor in ordering laboratory tests. Additionally, the providers agreed that the economic cost of testing was a greater consideration over guideline recommendations when deciding to order laboratory tests.

The results of the survey may also speak to the need for organization-level changes, rather than a focus on individual provider knowledge in order for CKD screening to increase. While survey participants mostly agreed that CKD was a priority for the organization, an example of *organization of healthcare*, there were varying levels of agreement about the ability of the organization to support increased screening (Figure 4). Although the EMR has decision support and feedback capabilities, means of operationalizing *clinical information systems* and *clinical decision support*, the current system does not facilitate specific guideline-recommended screening for CKD, and not all of the participants found the feedback mechanism useful. The survey participants also mentioned having actionable guidance, which could occur as built-in orders in the EMR or as a simple pocket guide to ordering, would increase recommended CKD screening. The Chronic Care Model element, *delivery system design*, was at the forefront of participants' write-in answers. The need for more human resources was evident in many of the survey responses. While there are nephrology services available within the organization, an improved connection to nephrology colleagues through e-consults or via nephrology chart reviews were offered as suggestions for increasing CKD screening. Additionally, survey participants mentioned the need for coordination of care for contacting patients for laboratory testing and follow up on those tests. Non-provider roles that were identified as options for this follow-up were patient care coordinator, medical assistant or registered nurse, or a population health manager. However, when participants were asked about organizational capacity to meet

these human resource needs, the responses ran the full gamut from “not at all” to “to a great extent” with the majority of the responses in the middle.

Figure 4. Provider -Identified Needs to Meet Specified Guideline Uptake



Note: N = 10 Provider responses

Discussion

The findings from this study offer a broadened view of the process of guideline-based screening for CKD in a hypertensive patient population using an organizational focus. CKD screening and recognition of CDK in the EMR problem list, the area of the medical record where current medical issues are listed, were low, which is consistent with current literature. The United States Renal Data System Annual Report notes a higher prevalence of CKD in the general population than there is a personal awareness of having the condition (United States Renal Data Systems (USRDS), 2017). Rao et al. (2013a) found low recognition of CKD on problem lists in a study of primary care clinics. Likewise, Plantinga, Tuot, Grubbs, Hsu, and Powe (2012) found that the addition of automated eGFR reporting on metabolic panels was not sufficient to ensure CKD recognition in the EMR problem list.

The way in which eGFR results are presented in the EMR in this organization (i.e., > 60 ml/min is normal) also reduces the ability of providers who are aware of the KDIGO recommendations to determine prognostic risk in patients with slightly decreased eGFR (between 60 and 90ml/min) who also have increased UACR levels. For providers who were not

familiar with the KDIGO Guidelines on screening or staging CKD, there was no direct access to or translation of these recommendations. The low rates of CKD screening could also be attributed to the lack of translation of CKD-specific recommendations in actionable practice and the lack of confidence in the guideline recommendations themselves. The providers agreed that there are other factors that influence their decision to order laboratory tests.

The survey respondents identified resources that could lead to increased screening for CKD in their organization. This desire for EMR decision support has been explored in other research, with Pefanis et al. (2016) finding that CKD screening significantly increased in when the EMR prompted providers to order laboratory tests during encounters with high-risk patients. Providers in the current study also self-identified increased nephrology involvement in CKD screening and staging. Lee et al. (2012) studied the impact of a population-based nephrologist who screened primary care records. They found an increase in metabolic panel ordering and a slowed progression of CKD in patients with stage 3a CKD. Electronic nephrology consults have been found to increase co-management of primary care patients with CKD and decrease the burden of traditional nephrology care visits (Mark et al., 2011; Smith et al., 2016). The other human resource needs identified by providers in the current study have also been addressed by other organizations. The SureNet program from Kaiser Permanente in California uses a parallel-care approach where a creatinine screening program is managed by a nurse manager and staffed by a licensed practical nurse (Sim et al., 2015).

The strength of this study is that the multiple sources of data that were analyzed for this study provided a wholistic view of CKD screening within one organization. This added a unique description of an organizational case with both the outcome of screening or CKD recognition and the factors influencing how the decisions to order laboratory tests are made. The organizational

case results were framed in the Chronic Care Model to identify areas where model elements were more prominently expressed. While this study offers a unique perspective on CKD screening in primary care in that different facets of data were all drawn from one organization, there are limitations. First, the percentage of survey participants was low (10%) and may not be a representative sample of primary care providers in this organization. Also, the intended EMR sample from each clinic was not obtainable. Additionally, the diagnostic codes for laboratory testing were not included in the deidentified dataset of patient records, therefore it was not possible to determine a reason behind the orders for metabolic or urine testing.

Conclusion

Despite low overall CKD screening rates, the testing patterns in high-risk patients were promising. Patients who were at highest risk for CKD related to their race, number of medications, and elevated systolic blood pressure were more likely to receive metabolic test orders, and as the numbers of risk factors increased, testing was more likely to occur. Survey participants thought CKD was an organizational priority and were open to receiving education or support to enhance the care they are able to provide patients. Guidelines themselves were not seen as prescriptive or the main drivers in CKD screening. Applying the Chronic Care Model as an organizational approach rather than focusing on individual provider practice may be a better solution to low CKD screening. Future research studies or quality improvement projects then should take a wholistic approach, rather than focusing on one improvement element, and should use the providers' input as to where resources are lacking as a starting point.

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Chapter 7

Antihypertensive Medications and Nephropathy Screening in a Primary Care Clinical Practice

Introduction

Early screening for chronic kidney disease (CKD) has been described as both clinically and economically beneficial (Kidney Disease: Improving Global Outcomes CKD Work Group, 2013, Supplement). The importance of identifying CKD in high-risk populations, such as individuals with diabetes or hypertension, has also been acknowledged by the U.S. Preventive Services Task Force (2012), the CKD Initiative by the Centers for Disease Control and Prevention (2015), and the CKD Objective in Healthy People 2020 (2015). Because nephrologists typically focus on later-stage CKD and end-stage renal disease (ESRD) management, primary care providers are then positioned for early screening and management of CKD in their patient populations. However, studies have shown there are gaps in primary care providers' confidence to identify, stage, and manage CKD according to current recommendations (Abdel-Kader et al., 2011; Abdel-Kader et al., 2014; Charles et al., 2009; Plantinga et al., 2012; Rao et al., 2013).

The purpose of this study was to describe current CKD guideline uptake in primary care practice related to screening and antihypertensive medication use. There were four specific aims for this secondary analysis. One was to identify CKD screening frequency in a cohort of young men taking anti-hypertensive medications. The study also sought to estimate CKD prognosis risk in the cohort based on Kidney Disease: Improving Global Outcomes (KDIGO) (2013) staging of laboratory results. Third, the study sought to describe anti-hypertensive medications prescribed

in this cohort by race and laboratory results. The final aim was to depict provider knowledge and attitudes towards CKD screening guideline recommendations.

Methods

This observational cross-sectional study involved secondary analysis of data collected in a larger organizational case study that was aimed at exploring multiple factors influencing ordering of CKD screening by urine albumin: creatinine ratio (UACR) in primary care patients with hypertension (see Chapter 6). All data were collected from five purposively-chosen primary care clinics within one academic medical center.

The study used a subsample of patient from the larger study and included 145 patient records selected because each was taking at least one anti-hypertensive medication. The same 12 providers who responded to the survey in the larger study were included in this analysis (response rate of 10%). Patient records were collected and de-identified by an external research institute. The dataset included patients with hypertension who did not have CKD or other medical diagnoses, were males aged 18-44, were African American or European American, and were prescribed anti-hypertensive medications. Primary care providers were invited to participate in the survey if they were currently practicing in one of the five designated clinics and included doctors, nurse practitioners, physician assistants, and medical residents. The survey was conducted in the REDCap system (Harris et al., 2009) and all answers were anonymous.

Variables of interest in the medical record dataset comprised anti-hypertensive medication class, laboratory orders and results for eGFR or UACR, insurance, race, and average systolic blood pressure across encounters. Provider survey variables were guideline awareness and utility, identification of CKD risk factors within their patient populations by selecting all appropriate answers from among identified response options, and responses to laboratory

ordering based on a clinical vignette. All providers received the same vignette involving a hypothetical patient. The clinical vignette was as follows.

> "Mr. Smith is a 25-year-old African American man coming to see you for the first time. The reason for his visit today is headaches. He states he has no significant past medical history and only takes Tylenol or Advil for pain. His vital signs are T-97.8, P-98, BP-178/98, O2-100%. When asked about his blood pressure, Mr. Smith says it has been high every time he gets checked at a doctor's office (maybe 2-3 visits) for the last 5 years, but that he has not been diagnosed with hypertension and doesn't take anything for it. He currently has Apple Health [Medicare] coverage."

More detail on data collection is described in detail elsewhere (see Chapter 6) and occurred in February through March of 2018. De-identified patient records were limited to calendar year 2016 and represent a random sample of patients with recorded encounters in the five chosen clinics.

Analysis

All data were analyzed at the organizational level as individual clinic membership did not significantly contribute to outcome measures. Survey responses were analyzed by descriptive statistics using Microsoft Excel. Medical record data were cleaned, and multiple encounters were consolidated into a summary variable using Microsoft Excel; more detailed information is in the larger study (see Chapter 6). Correlations and descriptive statistics were performed using IBM SPSS Statistics for Windows, Version 19.0. Armonk, NY: IBM Corp. There were very few missing data, which were coded as missing without imputation or mean substitution; no cases were removed from analysis.

Results

Medical Records

This patient cohort of 145 men taking anti-hypertensive medications was 39% African American 61% European American, and the mean age was 38 years old. This cohort includes

patients from all five clinics. Across this cohort, only 14% had a UACR test order and 53% had a metabolic panel test order (including the eGFR) during 2016 calendar year. Insurance was not a significant correlate to either type of testing ($p > 0.05$ in both types). A higher percentage of African American patients had both a metabolic test (63%) and the UACR test (19%) ordered compared to their European American counterparts (47% and 10% respectively). Table 1 presents patient insurance type and race by test ordering.

Table 1. CKD test ordering by patient insurance type and race in a cohort of African American and European American men in Primary Care Encounters

	Metabolic Panel				*UACR*					
	N = 145				*N = 145*					
	not done		done		not done		done		Total	
Insurance Type	N	%	N	%	N	%	N	%	N	%
Private	13	39	20	61	29	88	4	12	33	23
Medicare	2	40	3	60	5	100	0	0	5	3
Medicaid	40	50	40	50	66	83	14	18	80	55
Charity (none)	12	46	14	54	24	92	2	8	26	18
Missing	1	100	0	0	1	100	0	0	1	1
Race										
African American	21	37	36	63	46	81	11	19	57	39
European American	47	53	42	47	79	90	9	10	88	61

Note: UACR = urine albumin: creatinine ratio

Among the 77 men who had metabolic testing results in their record, the majority (95%) had eGFR results greater than 60 ml/min/1.73m^2 (the highest reported value at this organization). Only 55% of the 20 patients with UACR testing had normal results of less than 30 mg/g. Three patients had a UACR test ordered without a simultaneous metabolic panel, while 60 patients had only the metabolic test ordered. Results of a cross tabulation of eGFR levels by UACR levels are presented in Table 2. Seven patients met KDIGO staging as moderate risk and six as high risk for progression to ESRD.

Table 2. KDIGO CKD Risk Level and Staging Using eGFR and UACR

	UACR in mg/g	No Test	< 30 (normal)	30-300 (moderately increased)	>300 (severely increased)	Total
		N (risk)	*N (risk)*	*N (risk)*	*N (risk)*	
eGFR in ml/min/1.73m²	No test	65	1*	2 (MR)	0	68
	>60 (unable to stage)	58*	8 (LR)	2 (MR)	5 (HR)	73
	45-59 (3a)	1 (MR)	2 (MR)	0	0	3
	30-44 (3b)	1 (HR)	0	0	0	1
	Total	125	11	4	5	145

*Note: eGFR = estimated glomerular filtration rate, UACR = urine albumin: creatinine ratio, LR = low risk, MR = moderate risk, HR = high risk, * = unable to determine without simultaneous test results*

Pearson's correlations among race, metabolic panel and UACR testing, and medication types were performed to identify any significant relationships (Table 3). Race was positively correlated with thiazide diuretics ($r = 0.40$, $p < 0.001$). African American patients were prescribed a thiazide diuretic two times more often than their European American counterparts. Both metabolic testing and UACR testing were positively correlated with angiotensin-converting enzyme (ACE) inhibitors ($r = 0.24$, $p = 0.004$, $r = 0.24$, $p = 0.003$, respectively), and metabolic testing and UACR testing were positively correlated ($r = 0.26$, $p = 0.002$). ACE inhibitors were also found to be negatively correlated with calcium channel blockers (CCB) ($r = -0.34$, $p < 0.001$) and angiotensin II receptor blockers (ARB) ($r = -0.27$, $p = 0.001$). No other correlations were significant. The most common medication class prescribed in this cohort was ACE inhibitors (n = 49) followed by calcium channel blockers and thiazide diuretics (n = 28 each). Of the nine patients with elevated UACR levels, eight were taking an ACE or ARB and all but three were taking at least two classes of medications. Systolic blood pressures averaged across

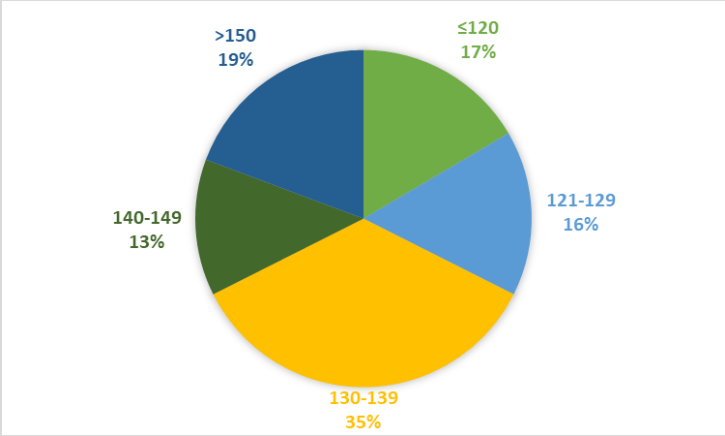
encounters are presented in Figure 1, and 68% of the cohort had an average systolic blood pressure less than 140mmHG.

Table 3.
Correlation Matrix of Anti-hypertensive Medications by CKD Screening

Measure	1.	2.	3.	4.	5.	6.	7.	8.	9.	10.
Outcomes										
1. Metabolic test	--									
2. UACR test	.26 **	--								
Predictors										
3. Race	.16	.13	--							
4. Angiotensin converting enzyme inhibitor	.24 **	.24 **	.05	--						
5. Angiotensin II Receptor blocker	-.14	.01	-.06	-.27 **	--					
6. Calcium channel blocker	-.02	-.06	.11	-.34 ***	.06	--				
7. Thiazide	.13	.03	.40 ***	.10	-.01	-.09	--			
8. Alpha-beta blocker	.10	.03	.16	-.05	.07	.09	.11	--		
9. Beta blocker	-.05	-.05	-.16	-.14	.02	-.06	-.08	-.09	--	
10. Apha andrinergic	.05	-.10	-.13	-.13	-.08	-.06	-.03	-.05	-.05	--

Note. N=145, UACR = urine albumin: creatinine ratio, * p < .05, ** p < .01, *** p < .001.

Figure 1.
Average Systolic Blood Pressure per Patient Across Encounters in mmHg

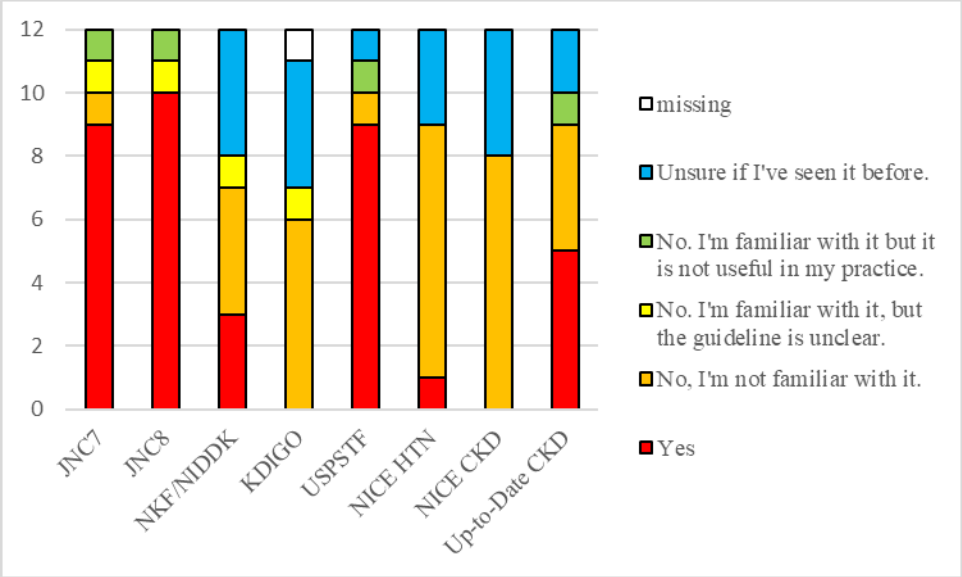


Provider Survey

The providers in this survey all had more than five years of experience as a provider, 75% trained as physicians and 50% were female, and represented four of the five clinics. Provider awareness and use of current recommendations varied. Many providers reported use of Joint National Committee 7 (70%) and 8 (80%) hypertension recommendations and the USPSTF recommendations, however, less than 20% reported use of National Kidney Foundation/National Institute of Diabetes and Digestive and Kidney Diseases guidelines. Only one provider reported knowledge of KDIGO guidelines but did not use it in practice because the guideline is unclear.

Figure 2 illustrates providers' familiarity with or use of the selected guidelines and recommendations.

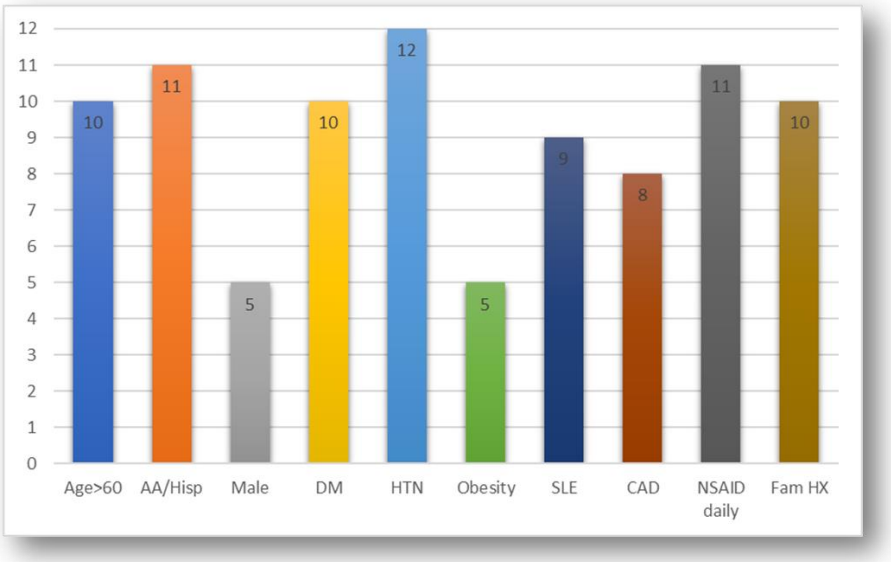
Figure 2.
Hypertension and CKD Guideline Awareness or Utility Noted by Providers



Note: JNC = Joint National Committee, NKF = National Kidney Foundation, NIDDK = National Institute for Diabetes and Digestive and Kidney Diseases, KDIGO = Kidney Disease Improving Global Outcomes, USPTSTF = United States Preventive Services Task Force, NICE = National Institute for Health and Care Excellence, HTN = hypertension, CKD = chronic kidney disease

Figure 3 illustrates the providers' choices for CKD risk in their patient populations. Overall, providers had good awareness of CKD risk factors with at least 75% correctly identifying hypertension, diabetes, coronary artery disease, systemic lupus erythematosus, older age, African American or Hispanic, daily nonsteroidal anti-inflammatory use, and family history. Obesity as a risk factor was correctly identified by less than half of the providers. Male sex was included as an incorrect distractor and was infrequently chosen.

Figure 3.
CKD risk factors selected by providers (N=12)



Note: AA = African American, Hisp = Hispanic, DM = diabetes mellitus, HTN = hypertension, SLE = systemic lupus erythematosus, CAD = coronary artery disease, NSAID = nonsteroidal anti-inflammatory drug, Fam HX = family history

Providers were asked to indicate their agreement with statements about laboratory tests they would order based on a presented clinical vignette. A fifth option was available for each question: “don’t know”. All providers agreed or strongly agreed that a serum creatinine and a reported eGFR would be useful to assess kidney disease and that they were confident in their ability to assess kidney function based on these test results. Providers responded with agreement or strong agreement that a UACR test (75%) or urinalysis (67%) were useful to assess kidney disease. For UACR, agreement with confidence in their ability to assess function based on results was 75% whereas only 50% felt confident using urinalysis results. Two providers did not know if ordering serum or laboratory tests or a urinalysis would be burdensome for the patient while four were not sure if the UACR test would be burdensome. When asked to identify any other tests the providers would order for this patient, eight providers offered responses including screening for diabetes, complete blood count, thyroid stimulating hormone, electrolytes, liver

function tests, lipids, renin: aldosterone ratio, urine protein: creatinine ratio, toxicology screen, and an EKG and renal ultrasound.

Discussion

Despite providers' awareness of hypertension as a CKD risk factor and confidence in their ability to assess CKD based on eGFR and UACR results, the rates of screening were low across this hypertensive population. However, when combined with the results of the survey, results are promising. Across other studies in the literature, providers demonstrated high awareness of diabetes and hypertension as CKD risk factors; however, the providers in this study also had higher reported awareness of the other CKD risk factors -- except for obesity -- when compared to other studies (Agrawal et al., 2008; Lea, McClellan, Melcher, Gladstone, & Hostetter, 2006). Similarly, the low awareness and use of CKD-specific guidelines echoes findings from other studies (Abdel-Kader et al., 2014; Agrawal et al., 2008; Lea et al., 2006). Providers in this organization have direct hyperlinks within the EMR to Up-to-Date™, the USPSTF, and the Agency for Healthcare Research and Quality sites, all of which include information on CKD guidelines or recommendations. However, within these website resources, CKD is often presented separately from the information about contributing diseases such as diabetes and hypertension. Thus, the limited use of CKD guidelines and recommendation reported by the providers is unsurprising.

The providers' responses to the questions about the hypothetical patient in the vignette and the guideline use and awareness indicate that the guidelines alone do not influence the decision to order screening tests. However, the trends in ordering did address many of the patient risk factors. For instance, African American patients more often received CKD screening tests compared to European American patients, which may reflect the providers' knowledge of race as

a risk factor for CKD as seen in the survey results. Correlations on the medical record data indicated that insurance status of the patient was not an indicator for differential test ordering. The burden of test ordering on the hypothetical patient in the vignette was not defined in the provider survey, but the low agreement with burden to the hypothetical patient may indicate that the providers in this organization did not limit screening for CKD to patients who had insurance coverage for those tests.

The reported maximum eGFR level was >60ml/min/1.73m^2. While this reflects the National Institute of Diabetes and Digestive and Kidney Diseases NIDDK recommendation not to report specific eGFR levels above this level (National Institute of Diabetes and Digestive and Kidney Diseases, 2018), it does not reflect the KDIGO CKD staging and risk assessment guideline, especially in the absence of a UACR level (KDIGO, 2013). None of the patients in this study had CKD on the problem list in their medical record, despite 9% of the patients meeting KDIGO risk for CKD progression. The lack of CKD recognition in the problem list is consistent with other studies (Jolly et al., 2014; Pefanis et al., 2016; Plantinga et al., 2012; Rao et al., 2013b; Samal, Linder, Bates, & Wright, 2014). Both Pefanis et al. (2016) and Samal et al. (2014) found higher levels of recommended CKD care when CKD was documented in the problem list.

The electronic medical record used at the organization requires a metabolic test order for patients on diuretics; however, thiazide diuretics were not significantly correlated with metabolic or UACR testing. The only anti-hypertensive medication class correlated with test ordering was ACE inhibitor. The only medication class correlated with race, specifically twice as often for African American compared to European American patients, was thiazide diuretics, which meets guideline recommendations for use of thiazide or CCB classes first in this population (James et

al., 2014). All but one patient with an elevated UACR was prescribed an ACE inhibitor or ARB, following guideline-recommended treatment of proteinuria (KDIGO, 2013). This cohort of patients also had good blood pressure control, with 68% meeting recommendations of systolic blood pressure of less than 140 mmHg (Bakken et al., 2008; Chobanian et al., 2003) compared to a reported 47% in the National Health and Nutrition Examination Survey (Yoon, et al, 2015).

Limitations

This study has several limitations. The diagnostic codes for test orders were not included in the de-identified dataset, therefore metabolic testing may not be indicative of CKD screening, as the panel includes a larger number of tests. The method of UACR testing was also not available, which raises the possibility of false positive results. Additionally, many of the patients only had one test result, which is insufficient to diagnose CKD (KDIGO, 2013). The low provider response rate is another limitation of the study. Providers who responded to the survey may have a greater interest in CKD, and the low response rate (10%) may not be representative of the greater provider population, possibly introducing bias in this area of the study; however, the response rate of 10% of the potential sample in the current study is not dissimilar to other email-based provider surveys (Abdel-Kader et al., 2014; Lea et al., 2006).

Conclusion

This study adds to the current literature because it combines test ordering behaviors in both clinical practice by EMR review and hypothetical situations with questions based on a clinical vignette within one organization. Overall, this patient population had good blood pressure control, and patients with documented elevated UACR levels were often taking a recommended medication to address proteinuria. The low CKD screening rates found in the medical records of this hypertensive population is interesting, because the providers were also

aware of CKD risk factors and agreed that both eGFR and UACR were useful tests for CKD screening. Additionally, despite their low awareness and use of CKD-specific recommendations or guideline, providers reported they were aware of and confident in their ability to assess kidney function by eGFR and UACR. A higher awareness of blood pressure recommendations was reflected in providers' management of systolic blood pressure, consistent with current guidelines. The guidelines themselves, then, do not appear to be a major factor in decisions about CKD screening. Future research should begin with and include providers and organizational leadership before interventions are established to better understand the needs and direction for increasing CKD screening.

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Chapter 8

Implications for Nursing Practice and Research

Overall, the providers in all of the studies were open to increasing CKD screening with proper support. The results of the three studies included in this dissertation offer insights into means of improving CKD screening by primary care providers. Nephrology nurses were highlighted in the scoping review as possible key resources for primary care diagnosis and management of CKD. The idea of multi-disciplinary coordinated care for in primary care settings was echoed in the provider written responses to the survey. There is also opportunity for Nurse Practitioners to bridge the gap between primary and nephrology care or to increase the capacity of the nephrology workforce as specialized providers.

Researchers have many opportunities to expand on the knowledge gleaned from this work. There is a need for increased education about CKD risk, diagnosis, and early management in primary care settings. How this education is delivered is yet to be determined. Health informatics may play a key role in disseminating information and offering clinical decision support, however end-users need to be brought into development of interventions early to stave off issues of feasibility and utility as seen in the results of the scoping review. Other interventions aimed guideline uptake need to first determine the barriers providers face in ordering and interpreting CKD screening as well as in availability of nephrology expertise.

Appendix A

Provider Survey

Thank you for taking the time to respond to this survey. My name is Sarah Llewellyn and I am a PhD candidate at the University of Washington. This survey is part of a larger study aimed at further understanding guideline uptake in your organization. Your responses to this survey are invaluable for a better understanding of your experiences as a provider within this organization and are not meant to test you.

I estimate it will take you about 30-45 minutes to complete the intial, multiple choice section of the survey. There is an optional open ended section at the end I hope you will also be able to complete. Your responses are anonymous, please only complete the survey once. By completing the survey, you report that you are currently providing primary care services and you consent to participating in this study.

As a thank you to you and your colleagues for completing the survey, a continental breakfast will be provided to your staff in the name of the physicians, nurse practitioners, physican assistants, and residents in your clinic.

Please complete the survey as soon as you are able, it will be available online until March 31, 2018.

If you have questions regarding the survey, you may contact me at: llewese@uw.edu.

Thank you.

Mr. Smith is a 25 year-old African American man coming to see you for the first time. The reason for his visit today is headaches. He states he has no significant past medical history and only takes Tylenol or Advil for pain. His vital signs are T-97.8, P-98, BP- 178/98, O2-100%. When asked about his blood pressure, Mr. Smith says it has been high every time he gets checked at a doctor's office (maybe 2-3 visits) for the last 5years, but that he has not been diagnosed with hypertension and doesn't take anything for it. He currently has Apple Health coverage.

		Strongly Agree	Agree	Disagree	Strongly Disagree	Don't Know
1)	Measurement of the patient's serum creatinine would be useful in assessing his kidney function.	○	○	○	○	○
2)	Ordering a serum creatinine would be unnecessary for this patient.	○	○	○	○	○
3)	Reporting an estimated glomerular filtration rate (eGFR) would be useful in assessing his kidney function.	○	○	○	○	○
4)						

	Results of an eGFR would be unnecessary for this patient.	○	○	○	○	○
5)	I am confident in my ability to assess kidney function based on these serum lab tests, if ordered.	○	○	○	○	○
6)	Ordering serum lab tests would be burdensome to the patient.	○	○	○	○	○
7)	Measurement of the patient's quantitative albuminuria (UACR) would be useful in assessing his kidney function.	○	○	○	○	○
8)	Ordering a UACR would be unnecessary for this patient.	○	○	○	○	○
9)	I am confident in my ability to assess kidney function based on an UACR test, if ordered.	○	○	○	○	○
10)	Ordering a UACR measurement would be burdensome to the patient.	○	○	○	○	○
11)	Ordering a UACR measurement would not be helpful due to poor reliability.	○	○	○	○	○
12)	Measurement of the patient's urinalysis (UA) would be useful in assessing his kidney function.	○	○	○	○	○
13)	Ordering a UA would be unnecessary for this patient.	○	○	○	○	○
14)	I am confident in my ability to assess kidney function based on a UA, if ordered.	○	○	○	○	○
15)	Ordering a UA would be burdensome to the patient.	○	○	○	○	○

16) Are there any other tests you would order for Mr. Smith?

_____

17) What are risk factors for chronic kidney disease (CKD) in the patients you see ? (Check all that apply)

- ☐ Age>60 years
- ☐ African American/Hispanic
- ☐ Male gender
- ☐ Diabetes Mellitus
- ☐ Hypertension
- ☐ Obesity
- ☐ Systemic Lupus Erythematosus
- ☐ Coronary Artery Disease
- ☐ Daily NSAID use
- ☐ Family history of CKD

Have these guidelines/recommendations/resources been helpful in managing your hypertensive patients, especially those who are at risk for kidney disease? Please select one answer per guideline:

	Yes	No, I'm not familiar with it.	No. I'm familiar with it, but the guideline is unclear.	No. I'm familiar with it but it is not useful in my practice.	Unsure if I've seen it before.
18) JNC7	○	○	○	○	○
19) JNC8	○	○	○	○	○
20) National Kidney Foundation/ NIDDK	○	○	○	○	○
21) KDIGO (Kidney Disease International)	○	○	○	○	○
22) US Preventative Services Task Force	○	○	○	○	○
23) NICE (UK) Hypertension	○	○	○	○	○
24) NICE (UK) CKD Identification and Management	○	○	○	○	○
25) Up-to-Date Screening for CKD	○	○	○	○	○

26) Which of the following interventions would most appeal to you to help optimize your identification and management of patients with CKD? (check all that apply)

- ☐ Continuing medical education lectures (CME)
- ☐ Collaborative practice agreements (i.e., practice based management with the help of pharmacists or physician)
- ☐ Electronic health record clinical decision support (e.g., real-time clinical reminders within workflow)
- ☐ Academic detailing by CKD specialist-nephrologist
- ☐ Audit and feedback on clinical performance
- ☐ None of the above

27) To what extent do you feel CKD identification is a priority at your organization?

- ○ To a great extent
- ○ Somewhat
- ○ Very little
- ○ Not at all

28) What is your current primary care role?

- ○ MD/DO provider
- ○ NP/PA provider
- ○ Resident physician

29) How many years has it been since you completed your training?

- ○ In residency
- ○ less than 5 years
- ○ 5-10 years
- ○ >10 years

30) How many years have you practiced at this organization?

- ○ only during residency
- ○ less than 1 year
- ○ 1-5 years
- ○ 6-10 years
- ○ > 10 years

31) What is your employment status?
- ◯ Full time (>75%)
- ◯ Part time(< 75%)
- ◯ Contract
- ◯ Resident
- ◯ Other

32) Race/Ethnicity, select all that apply
- ☐ White
- ☐ Black/AA
- ☐ Asian
- ☐ AI/AN
- ☐ Hispanic/Latinx
- ☐ Prefer not to answer

33) Gender Identity
- ◯ Male
- ◯ Female
- ◯ Non-binary
- ◯ Prefer not to answer

34) Clinic to which you are primarily assigned
- ◯ Adult Medical Clinic Harborview
- ◯ Family Medicine Clinic Harborview
- ◯ General Internal Medicine Roosevelt
- ◯ Pioneer Square Clinic
- ◯ Third Ave Center
- ◯ Hall Health

35) Are you willing to complete an additional set of questions about clinical practice guidelines?
- ◯ Yes
- ◯ No

Optional Section

36) Please describe your views on clinical practice guidelines in general

_____

37) If your organization chose to adopt a new clinical practice guideline for identification of kidney disease, what type of educational resource would be most helpful for you to incorporate the new guideline recommendations into your practice (and why most helpful)?

_____

38) To what extent do you agree that your organization has the capacity to support those educational resource needs?
- ◯ To a great extent
- ◯ Somewhat
- ◯ Very little
- ◯ Not at all

39) If your organization chose to adopt a new clinical practice guideline for identification of kidney disease, what type of human resource would be most helpful for you to incorporate the new guideline recommendations into your practice (and why most helpful)?

_____

40) To what extent do you agree that your organization has the capacity to support those human resource needs?
- ◯ To a great extent
- ◯ Somewhat
- ◯ Very little
- ◯ Not at all

41) If your organization chose to adopt a new clinical practice guideline for identification of kidney disease, what type of technological resource would be most helpful for you to incorporate the new guideline recommendations into your practice (and why most helpful)?

_____

42) To what extent do you agree that your organization has the capacity to support those technological resource needs?

- ◯ To a great extent
- ◯ Somewhat
- ◯ Very little
- ◯ Not at all

43) What type of monitoring or feedback do you receive from your organization, if any, about your practice in regards to guideline based care?

_____

44) To what extent do you agree that your practice is impacted by monitoring or feedback from your organization?

- ◯ To a great extent
- ◯ Somewhat
- ◯ Very little
- ◯ Not at all

45) To what extent do patient preferences influence whether or not you order guideline recommended tests or procedures?

- ◯ To a great extent
- ◯ Somewhat
- ◯ Very little
- ◯ Not at all

46) Some guideline recommended tests are tied to clinic level reimbursement or incentive structures, to what extent do these financial incentives influence whether or not you order those tests?

- ◯ To a great extent
- ◯ Somewhat
- ◯ Very little
- ◯ Not at all

47) To what extent do you prioritize economic costs of testing versus the guideline recommendations?

- ◯ To a great extent
- ◯ Somewhat
- ◯ Very little
- ◯ Not at all

Appendix B

UNIVERSITY of WASHINGTON
HUMAN SUBJECTS DIVISION

NOT HUMAN SUBJECTS

January 16, 2018

Dear Sarah Llewellyn:

On 01/16/18 the University of Washington Human Subjects Division reviewed the following application:

Type of Review:	Initial Study
Title of Study:	Electronic Health Records Review: Hypertensive Chronic Kidney Disease Identification in Primary Care
Investigator:	Sarah Llewellyn
IRB ID:	STUDY00003956
Funding:	None
IND, IDE, or HDE:	None

The Human Subjects Division determined that the proposed activity does not involve human subjects, as defined by federal and state regulations. Therefore, review and approval by the University of Washington IRB is not required.

This determination applies only to the activities described in this application. **Depending on the nature of your study, you may need to obtain other approvals or permissions to conduct your research. For example, you might need to apply for access to data (e.g., to obtain UW student data). Or, you might need to obtain permission from facilities managers to approach possible subjects or conduct research procedures in the facilities (e.g., Seattle School District; the Harborview Emergency Department).**

If you need to make changes in the future that may affect this determination or are not sure, contact us to see if you need to submit a new application.

We wish you great success.

Sincerely,

Leah M. Miller, PhD
Team Operations Lead, IRB-D and Team D
lemiller@uw.edu
(206) 543-2977

UNIVERSITY of WASHINGTON
HUMAN SUBJECTS DIVISION

DETERMINATION OF EXEMPT STATUS

January 24, 2018

Dear Sarah Llewellyn:

On 1/24/2018, the University of Washington Human Subjects Division (HSD) reviewed the following application:

Type of Review:	Initial Study
Title of Study:	Hypertensive Chronic Kidney Disease Identification Survey of Primary Care Clinicians
Investigator:	Sarah Llewellyn
IRB ID:	STUDY00003962
Funding:	None

Exempt Status

HSD determined that your proposed activity is human subjects research that qualifies for exempt status (Category 2).

- This determination is valid for the duration of your research.
- This means that your research is exempt from the federal human subjects regulations, including the requirement for IRB approval and continuing review.
- **Depending on the nature of your study, you may need to obtain other approvals or permissions to conduct your research. For example, you might need to apply for access to data (e.g., to obtain UW student data). Or, you might need to obtain permission from facilities managers to approach possible subjects or conduct research procedures in the facilities (e.g., Seattle School District; the Harborview Emergency Department).**

If you consider changes to the activities in the future and know that the changes will require IRB review (or you are not certain), you may request a review or new determination by submitting a Modification to this application. For information about what changes require a Modification, refer to the **GUIDANCE: Exempt Research**.

Thank you for your commitment to ethical and responsible research. We wish you great success!

Sincerely,

Leah M. Miller, PhD
Team Operations Lead, IRB-D and Team D
lemiller@uw.edu
(206) 543-2977

Appendix C

Copyright clearance for use of the Chronic Care Model image

American College of Physicians LICENSE TERMS AND CONDITIONS

License Number	4345971273032
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Requestor type	Publisher, not-for-profit
Format	Electronic
Portion	image/photo
Number of images/photos requested	3
The requesting person/organization is:	Sarah Llewellyn
Title or numeric reference of the portion(s)	Chapter 3, Figure 1; Chapter 5, Figure 1; Chapter 6, Figure 1