

## ORIGINAL RESEARCH

# Chronic Kidney Disease Guideline Implementation in Primary Care: A Qualitative Report from the TRANSLATE CKD Study

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**Background:** Primary care physicians (PCPs) are optimally situated to identify and manage early stage chronic kidney disease (CKD). Nonetheless, studies have documented suboptimal PCP understanding, awareness, and management of early CKD. The TRANSLATE CKD study is an ongoing national, mixed-methods, cluster randomized control trial that examines the implementation of evidence-based guidelines for CKD into primary care practice.

**Methods:** As part of the mixed-methods process evaluation, semistructured interviews were conducted by phone with 27 providers participating in the study. Interviews were audio-taped and transcribed. Thematic content analysis was used to identify themes. Themes were categorized according to the 4 domains of Normalization Process Theory (NPT).

**Results:** Identified themes illuminated the complex work undertaken to manage CKD in primary care practices. Barriers to guideline implementation were identified in each of the 4 NPT domains, including (1) lack of knowledge and understanding around CKD (coherence), (2) difficulties engaging providers and patients in CKD management (cognitive participation), (3) limited time and competing demands (collective action), and (4) challenges obtaining and using data to monitor progress (reflexive monitoring).

**Conclusions:** Addressing the barriers to implementation with concrete interventions at the levels at which they occur, informed by NPT, will ultimately improve the quality of CKD patient care. (J Am Board Fam Med 2015;28:624–631.)

**Keywords:** Chronic Renal Diseases, Normalization Process Theory, Primary Health Care, Qualitative Research

The prevalence of chronic kidney disease (CKD) is increasing in the United States.<sup>1</sup> Patients with CKD often suffer from other comorbidities and risk factors, such as diabetes, hypertension, hypercholesterolemia, and obesity, which add to com-

plexity and an increased risk of progression.<sup>2–5</sup> Early identification may result in better outcomes, such as slowed or halted progression to end-stage renal disease.<sup>2,4,6,7</sup>

Primary care physicians are optimally situated to identify and manage early stage CKD (stage 3, defined as at least 2 consecutive estimated glomerular filtration rates (eGFR) <60 mL/min at least 3 months apart).<sup>3,8</sup> The majority of patients with CKD (>60% by 1 estimate) are treated exclusively by primary care physicians.<sup>9</sup> Despite this, numerous studies have documented that primary care physicians' understanding, awareness, and adequate management of early CKD are lacking, and CKD is generally under-recognized and undertreated by primary care physicians.<sup>9–14</sup>

Implementing established evidence-based guidelines for CKD in practice has proven challenging for

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multiple reasons.<sup>6,12</sup> First, despite the guidelines, there remains a lack of agreement on the definition of CKD, treatment, and staging,<sup>13,15–17</sup> and concerns about overdiagnosis, especially among elderly patients, persist.<sup>13,18</sup> Other reasons for slow uptake of the guidelines include limited time to see patients,<sup>1,16</sup> limited understanding of the current guidelines,<sup>9,10</sup> and lack of educational and administrative resources, including quality indicators, to support CKD care.<sup>9,12,14,16</sup> Studies have also documented provider discomfort with disclosing and discussing CKD with patients because of providers' uncertainty about the disease and concerns about frightening patients.<sup>13,16,17</sup>

Despite the demonstrated benefits of evidence-based medicine, the process of translating research to clinical application can be arduous, tedious, and lengthy.<sup>18</sup> Theory may help illuminate the barriers and facilitators to implementation and inform interventions.<sup>19</sup> Normalization Process Theory (NPT) has proven useful in understanding the work involved in implementing and integrating new practices into health care settings.<sup>13,20–23</sup> NPT provides a framework for examining implementation processes by dividing the “work” of integrating new practices into 4 domains: (1) coherence or sense-making, involving developing an understanding of the task and one's role; (2) cognitive participation or relationship work, involving organizing personnel and resources around a task; (3) collective action, or operationalizing and engaging in a task; and (4) reflexive monitoring, which includes appraising progress on a task and its effects.<sup>24</sup> Blakeman et al<sup>13</sup> used this approach to examine the management of early stage CKD in primary care in Britain, focusing on the difficulties faced by providers in identifying and discussing early stage CKD with patients and the embedding of CKD care into discussions about vascular care. Another study used NPT to examine the implementation of nutritional guidelines in nursing homes, finding that the theory was especially useful to conceptualizing the barriers to implementation by identifying concrete domains (e.g., coherence, collective action) for intervention.<sup>20</sup> We applied NPT to better understand and illuminate facilitators and barriers to primary care physicians' adoption and implementation of evidence-based CKD guidelines, as part of a multisite study, TRANSLATE CKD.

The TRANSLATE CKD study is an ongoing national, mixed-methods, cluster randomized con-

trol trial that examines the implementation of evidence-based guidelines for CKD into primary care practice. A complete study protocol has been published elsewhere.<sup>25</sup> Thirty-eight primary care practices from across the United States are enrolled in the study. The study compares the effectiveness of CKD-specific computer-decision support (CDS) alone versus CKD CDS plus virtual practice facilitation in implementing evidence-based care and improving outcomes for patients with stage 3 and 4 CKD in primary care practices. A mixed-methods process evaluation is being conducted with the intervention sites to assess the impact of virtual practice facilitation, assess the success of practice transformation, and identify barriers and facilitators to improving CKD care in primary care practices. As part of the process evaluation, semistructured qualitative interviews were conducted at baseline (i.e., randomization) with clinicians from all the intervention (virtual facilitation + CDS) practices and a sample of the comparator (CDS alone) practices to assess CKD-related knowledge and practices.

## Methods

### *Participants*

Practices who enrolled in the TRANSLATE-CKD study were asked to identify a clinician who would take responsibility for leading the project in their practice. Interviews were conducted with all the lead clinicians from the intervention practices and with a convenience sample of clinicians from the comparator practices. Practices were enrolled and randomized in 3 phases in November 2012, May 2013, and May 2014. Baseline for each practice was considered to be the time of randomization, before initial academic detailing and the commencement of practice facilitation.

### *Research Team*

The evaluation team for the TRANSLATE-CKD study was led by a PhD medical anthropologist (LSK) with experience in health services research, evaluation, and mixed-methods projects. Other team members included a PhD medical anthropologist (BMV), a health services researcher (JS) trained in qualitative methods, and a medical student (TRMY). Findings were shared with the principal investigator (CHF), a family physician researcher with extensive clinical and research experience related to CKD and practice transformation projects. The diversity of clinical, so-

**Table 1. Clinician Interview Questions**

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- 1) We are so glad you have decided to participate in this study. What factors contributed to your decision to participate?
  - 2) What is your sense of how receptive others in your practice are to getting involved in this project?
  - 3) Tell me about the general level of support in your organization for practice improvement projects.
    - a. When you begin a project, how do you identify patients who are in the target population?
  - 4) Tell me about opportunities in your organization/practice to engage in other types of provider and staff education?
  - 5) In general, tell me how your practice uses evidence-based guidelines in the treatment of your patients with chronic disease.
    - a. Are you aware of national guidelines for CKD?
    - b. Has your practice discussed national guidelines as a group?
    - c. Has your practice taken steps to incorporate national guidelines for CKD?
  - 6) Who do you consider to be at risk for CKD?
  - 7) Do you screen regularly for CKD in those patients you just mentioned who are at risk?
    - a. If yes, which tests do you use?
    - b. If no, why not?
  - 8) Which criteria does your practice use to justify a diagnosis of CKD?
    - a. How do you document the diagnosis?
  - 9) What do you tell your patients when they are first diagnosed with CKD?
    - a. How do you describe CKD to your patients?
  - 10) In general, how do you monitor the care of your patients with chronic diseases such as CKD?
    - a. What type of system do you use to track and follow these patients (in terms of need for lab work, preventive services, etc.)?
    - b. Describe the process your staff uses to work together to care for patients with CKD.
  - 11) A lot of practices use performance measures for feedback. What kind of system does your practice have in place?
  - 12) What challenges do you face in caring for your patients with CKD?
  - 13) Is there anything else you would like to share about your experiences:
    - a. Taking care of patients with CKD?
    - b. Implementing practice improvement projects?
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CKD, chronic kidney disease.

cial science, and health services perspectives allowed for validation of study findings and helped to reduce potential disciplinary bias.

### **Data Collection**

Clinicians participated in semistructured interviews conducted by telephone. Most interviews were conducted by a member of the study evaluation team (LSK, BMV, and JS). Because of constraints on clinicians' time and the need to streamline contacts and study activities for the practice, however, a few interviews ( $n = 9$ ) also were conducted by the practice facilitator assigned to particular intervention practices. All the interviews were conducted before the intervention period, and therefore the practice facilitators had no prior relationship with the practices and were not engaged in any intervention activities. The interview represented a first contact, minimizing any potential bias. Interviews were recorded and transcribed. Most interviews lasted approximately 30 minutes.

Three phases of interviews were conducted with practices, corresponding to each practice's "baseline" (i.e., each phase of randomization). All interviews

were conducted before the practice or lead clinician engaged in any intervention activities to describe CKD care before the start of the study intervention.

Clinicians were asked about their current knowledge and practices in identifying, diagnosing, and managing patients with CKD and their knowledge of national CKD guidelines. Participants also were asked about general processes in their office related to population health management (e.g., use of registries, computer decision support, team approaches to care) and quality improvement (e.g., use of performance data, previous or concurrent engagement in quality improvement projects) (Table 1). The study protocol was approved by the Institutional Review Boards at the State University of New York at Buffalo and the American Academy of Family Physicians National Research Network. All participants provided informed consent for their participation in both the larger TRANSLATE CKD study and the qualitative interviews.

### **Data Analysis**

Interview transcripts were analyzed using a thematic content-driven approach whereby research-

**Table 2. Characteristics of Clinicians Participating in the Baseline Interviews**

	Participants (n)
Study assignment	
Intervention	18 (of 18)
Comparator	9 (of 16)
Clinician sex	
Male	19
Female	8
Clinician training	
MD	24
PA/NP	3

NP, nurse practitioner; PA, physician assistant.

ers repeatedly read through the data to identify emerging themes.<sup>26–28</sup> Each member of the evaluation team reviewed the transcripts independently and identified themes. The team then met several times to compare themes, resolve discrepancies, clarify meanings, and agree on a final organization of themes, subthemes, and details.<sup>27,29</sup> All disagreements about themes and organization were discussed until consensus was reached.

Analysis occurred in an iterative fashion over several phases. Initial themes were identified from the first round of interviews (November 2012 to February 2013) and then were expanded and adjusted over the course of 2 additional rounds of interviews (May June 2013 and May to August 2014). Saturation, defined as “the point in data collection and analysis when new information produces little or no change to the codebook,”<sup>30</sup> was reached after the first 2 rounds of analysis, and no new themes were identified in the third group of interviews.

After analysis was complete, identified themes were organized and categorized using the NPT constructs. This organization of themes led to framing the findings as barriers to incorporating evidence-based CKD care into practice in each of the 4 NPT construct areas.<sup>20,24</sup>

## Results

Twenty-seven clinicians were interviewed. Basic characteristics of the clinicians who participated in the interviews are displayed in Table 2.

Baseline interviews assessed current practice around CKD and chronic disease management. Themes related to current CKD practice were or-

ganized into each of the 4 components of NPT: coherence, cognitive participation, collective action, and reflexive monitoring.

### Coherence

Interviews revealed that providers struggled with coherence, or sense-making, related to CKD. Defining the task of CKD care was hindered by limited awareness and knowledge of CKD guidelines. While some providers reported knowledge of current guidelines, others were aware of only portions of the guidelines or admitted having no knowledge: “[We are] using the document as a guideline . . . we may talk indirectly about the guideline when we stress the importance of blood pressure, doing micros, etc.”

As a result, implementation of the guidelines was inconsistent. Providers discussed using portions of the guidelines and trying to incorporate them into their electronic medical records, but they frankly admitted that the use of guidelines varied widely by provider within the practice. Providers most commonly mentioned trying to use the guidelines to diagnose patients using the appropriate CKD stages, but they were less familiar with other aspects.

Responses to questions about screening and diagnostic criteria varied widely, from the use of eGFR, to creatinine, to blood urea nitrogen and “renal function tests.” Providers often discussed multiple tests and considerations, rather than referring primarily to 1 set of numbers. As a result, discussions about diagnosis also illustrated a wide variation in practice. While some providers assigned CKD diagnoses according to stage (using ICD-9 codes 585.1 to 5), others diagnosed the decline in kidney function as a manifestation of a comorbidity, such as diabetes or hypertension, and did not indicate a stage: “If diabetic, we may use diabetes with renal manifestation. . . . If he’s hypertensive we’ll do hypertension with history of chronic kidney disease stage 1 through 4,” and “go by the scale they have, chronic kidney disease stage 1, 2, 3, 4 and I see where their GFR lines up with that, and then that is how I diagnose what stage they are in.”

Providers often mentioned using guidelines in place for other diseases to cover CKD as well: “I do not follow one specific national guideline for CKD. A lot of it I incorporate with regards to the disease process . . . on whether it is a diabetic

patient with chronic disease, a hypertensive patient with CKD. . . .”

Providers expressed that their uncertainty over CKD guidelines, diagnosis, and treatment resulted from 2 main factors. First, they cited a lack of education available to them about CKD, in the form of continuing medical education, despite their desire to learn more and better manage their patients. Second, providers discussed the challenge of keeping up with guidelines that are constantly changing, making it difficult to know which guidelines to follow.

All this uncertainty was reflected in a lack of confidence around their ability to identify, diagnose, and treat patients with early CKD. Providers expressed discomfort in diagnosing CKD; 1 provider said that she refers patients to nephrology and does not make the diagnosis herself or discuss the issue with her patients: “I do not tell them because I am not comfortable enough . . . numbers do not look good. I need you to see a specialist, and they are the one that says it.”

Others expressed uncertainty over how to talk to their patients about CKD, admitting that they “skirt the issue,” partly because it opens up a “whole bag of worms” in the form of questions that the physician is not ready or able to address. Providers also mentioned not using the label of CKD, instead couching the conversation within a discussion of normal kidney decline that occurs with age or as a result of other comorbid conditions. Many mentioned explaining to a patient that they are monitoring their kidneys, which are not working as well as they used to, and emphasized controlling hypertension and diabetes as protective measures against further decline in kidney function. The uncertainty and inconsistency of practice around CKD and limited knowledge of national evidence-based guidelines represent serious barriers to coherence that limit providers’ ability to integrate CKD care into practice.

### ***Cognitive Participation***

Aside from their difficulties with sense-making around CKD, providers’ responses also reflected barriers to cognitive participation, or relationship work. Organizing staff and resources to the task of managing CKD and other chronic diseases often was challenging.

In part, the lack of coherence around CKD contributed to limited physician buy-in. Keeping up

with changing guidelines and educating staff and providers was cited as a difficulty. Beyond that, many providers felt overwhelmed by the challenges of the current health care climate and the shift to a focus on population health management. While participants discussed being engaged in quality improvement and practice transformation, they also expressed reservations over the changes.

Providers raised concerns over the heavy emphasis on technology in new models of care, which is expensive, difficult to learn, and sometimes overwhelming. Similarly, providers struggled with data collection and management and a sense that there are “too much data” and too many measures to collect across too many initiatives. Population health management was seen as a big job, which was challenging for small or private practices. As 1 physician said, “A lot of physicians do not feel they have the skills to do this in private practice.” The amount of resources and staff time necessary, coupled with a perception of limited reimbursement for the type of work required to do population health management, left respondents feeling ambivalent about fully engaging. As 1 respondent said, “Gone are the days a nurse could come in and work part-time—every job now takes 3 years to learn.”

Finally, in terms of organizing people to the task of CKD management, providers cited patient motivation, engagement, and adherence as significant barriers. Providers discussed how their ability to improve care was complicated by patients they described as nonadherent or unmotivated to make lifestyle changes and engage in self-management. When asked about their biggest challenge caring for patients with CKD, 1 provider said “getting the patients to care as much as I do.” Some providers also indicated difficulties in patient adherence with appointments. These logistic and resource-related issues hinder cognitive participation and buy-in to changing care processes for patients with CKD.

### ***Collective Action***

Even when providers expressed knowledge about CKD and willingness to dedicate time and resources to improving CKD care, they often encountered several areas that hindered their ability to move their efforts into collective action. Limited time and competing demands were constant challenges mentioned by providers. In this environment of constant quality improvement and practice transformation, providers often are engaged in

multiple initiatives, projects, and research studies simultaneously, making it difficult to prioritize and do everything well. As 1 provider said, “It is very easy to forget 1 of the 6 to 10 things that we’re supposed to be doing for people.”

Collective action also was hindered by a lack of resources and staff support, such as staff to serve in care manager roles. Providers also discussed varying levels of team-based care. While some discussed having coordinated staff processes, including standing orders, huddles, and population management coordinators, others indicated limited team processes.

Technological limitations represented another barrier to collective action. The lack of ability to generate patient registries and track patient needs and visits was cited as a logistic problem for many. While providers wanted to improve patient care, their efforts often were hindered by limited EMR systems, technological difficulties, and inaccurate data.

On the patient side, providers cited numerous logistic and economic barriers that made improvements in patient health difficult. These included patient lack of education and understanding of their disease, transportation limitations, social determinants of patient health, and insurance restrictions on lab tests, medications, and high deductibles.

### **Reflexive Monitoring**

Finally, providers discussed barriers to reflexive monitoring, or their ability to monitor progress they had made and make adjustments. Providers described the difficulties they experienced implementing audit and feedback processes for CKD. While they receive insurance reports and performance data from other sources, such as accountable care organizations and regional quality improvement organizations, none of this information is specific to CKD. Providers also expressed mixed opinions regarding the usefulness and accuracy of such information, especially insurance company reports.

Many providers discussed how they take it on themselves to monitor their progress by running internal reports, using registries, and printing summaries from the electronic medical record. However, others expressed limited ability to do audit and feedback and monitor progress because of a range of factors. Some explained that technological limitations may impede capturing scanned data or generating meaningful reports. Other physicians noted that their practices had the technological

capabilities, but they were unable to devote the time to learning how to use the functions. Overall, physicians reported that data collection and management were difficult and time-consuming, which inhibited reflexive monitoring of progress.

### **Discussion**

The results of our study highlight barriers to physician understanding, awareness, and comfort in diagnosing and managing early CKD among primary care patients. It has been almost a decade since a study by Fox et al<sup>9</sup> reported knowledge gaps and suboptimal physician practices surrounding early CKD in the primary care setting. Those observations included lack of awareness of evidence-based guidelines; desire for more CKD practice guidance; persistence of traditional, less accurate diagnostic procedures and almost no awareness of eGFR; variability in the treatment of complications with CKD; and, finally, uncertainty over when to refer to a nephrologist.<sup>9</sup> Providers interviewed in the present study expressed similar comments but demonstrated more awareness of the use of eGFR as an indicator of kidney disease, often listing it as one of many tests they used to make a diagnosis. Overall, our results support those of other studies that indicate continued low awareness and primary care provider uncertainty around CKD.<sup>9,10,12,13,16</sup> Informed by NPT, we expand on the results of these studies by examining factors beyond those of provider knowledge and understanding (coherence) to identify practice-level, system-level, and other factors that serve as additional barriers to implementing evidence-based care for CKD. In a previous study, Blakeman et al<sup>13</sup> also used NPT to understand management of early stage CKD in primary care offices in the United Kingdom. Similar to our findings, they reported provider discomfort discussing early CKD with patients and expressed concerns about provoking patient anxiety. They noted that this discomfort often was resolved by embedding CKD care in discussions of vascular care and sharing the ongoing responsibility for reassuring patients with the entire practice staff.<sup>13</sup> The current study expands on this analysis by examining CKD care beyond initial explanatory discussions with patients to explore the broader context and competing demands faced by physicians who are involved in providing ongoing CKD management. Our study identifies barriers to these activities across all 4 NPT domains.

Providers in our study reported engaging in population health management, using health information systems, team processes, and other practices in the management of their chronic disease patients, but in most cases they had not extended these practices to CKD care. Provider use of resources for the management of some conditions over others may, in part, be because of discomfort with the management of CKD. It is also likely a factor of secular forces in health care that have encouraged physicians to prioritize other chronic conditions, such as diabetes, as key targets for improvements in care. Physicians in our study largely rely on evidence-based diabetes and hypertension guidelines rather than those for CKD mainly because of a lack of knowledge about CKD guidelines. Lack of knowledge of CKD and subsequent inadequate practice modification and resource utilization may be the result of several factors that relate to NPT constructs: (1) lack of coherence around the guidelines, (2) lack of engagement around CKD care (cognitive participation and collective action), and (3) lack of feedback (reflexive monitoring).

### **Limitations**

This study had several limitations. First, data are based on clinician self-report of knowledge and practice processes. While clinicians may have reported knowledge and effective management of CKD and other chronic diseases, it is difficult to compare this information with their actual practice patterns and data. In addition, responses from the lead clinician may not be representative of all clinicians at that practice. Participants often acknowledged that they could speak only about their personal approaches to CKD diagnosis and treatment, noting that other providers at the practice did things differently. Finally, this study consisted of a small sample of providers who self-selected to participate in the TRANSLATE CKD study. Many of these providers were already using CDS for other conditions and participating in other research projects and quality improvement activities, and therefore they may not be representative of primary care providers in general.

### **Clinical Implications**

Framing the results from our provider interviews using NPT enabled us to identify key barriers and critical junctures where interventions need to occur to address these barriers.<sup>20</sup> In addition, NPT can guide the choice of interventions likely to be most

effective, whether they are cognitive versus tangible or practice versus process, and so on. For example, the lack of coherence around CKD may best be addressed by academic mentoring from clinical experts in CKD, whereas the lack of reflexive monitoring might be addressed by providing practices with data management systems and personnel. The TRANSLATE CKD trial currently underway is using some of these strategies in a multifaceted intervention to address some of these barriers across each of the NPT constructs. For example, academic mentors meet monthly with the primary care clinicians to discuss clinical questions related to CKD and to reinforce the guidelines (coherence and cognitive participation), while a data team pulls and compiles practice-level performance data to assist practices in monitoring their progress (reflexive monitoring) and practice facilitators engage with practices in quality improvement projects to improve workflows and processes around CKD (cognitive participation and collective action).

Properly identifying physician barriers and facilitators to guideline-concordant, efficient management of CKD is paramount in addressing the rising prevalence of CKD. It is important to recognize that the transition from the establishment of guidelines to actual implementation is an arduous process,<sup>19</sup> with barriers at many levels. Addressing the barriers to implementation, informed by NPT, at the levels at which they occur will ultimately increase the utilization of evidence-based guidelines for CKD and improve the quality of patient care.<sup>31</sup>

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