Impact of a Primary Care CKD Registry in a US Public Safety-Net Health Care Delivery System: A Pragmatic Randomized Trial

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Background: Many individuals with chronic kidney disease (CKD) do not receive guideline-concordant care. We examined the impact of a team-based primary care CKD registry on clinical measures and processes of care among patients with CKD cared for in a public safety-net health care delivery system.

Study Design: Pragmatic trial of a CKD registry versus a usual-care registry for 1 year.

Setting & Participants: Primary care providers (PCPs) and their patients with CKD in a safety-net primary care setting in San Francisco.

Intervention: The CKD registry identified at point of care all patients with CKD, those with blood pressure (BP) > 140/90 mm Hg, those without angiotensin-converting enzyme (ACE) inhibitor/angiotensin receptor blocker (ARB) prescription, and those without albuminuria quantification in the past year. It also provided quarterly feedback pertinent to these metrics to promote "outreach" to patients with CKD. The usual-care registry provided point-of-care cancer screening and immunization data.

Outcomes: Changes in systolic BP at 12 months (primary outcome), proportion of patients with BP control, prescription of ACE inhibitors/ARBs, quantification of albuminuria, severity of albuminuria, and estimated glomerular filtration rate.

Results: The patient population (n = 746) had a mean age of 56.7 ± 12.1 (standard deviation) years, was 53% women, and was diverse (8% non-Hispanic white, 35.7% black, 24.5% Hispanic, and 24.4% Asian). Randomization to the CKD registry (30 PCPs, 285 patients) versus the usual-care registry (49 PCPs, 461 patients) was associated with 2-fold greater odds of ACE inhibitor/ARB prescription (adjusted OR, 2.25; 95% CI, 1.45-3.49) and albuminuria quantification (adjusted OR, 2.44; 95% CI, 1.38-4.29) during the 1-year study period. Randomization to the CKD registry was not associated with changes in systolic BP, proportion of patients with uncontrolled BP, or degree of albuminuria or estimated glomerular filtration rate.

Limitations: Potential misclassification of CKD; missing baseline medication data; limited to study of a public safety-net health care system.

Conclusions: A team-based safety-net primary care CKD registry did not improve BP parameters, but led to greater albuminuria quantification and more ACE inhibitor/ARB prescriptions after 1 year. Adoption of team-based CKD registries may represent an important step in translating evidence into practice for CKD management.

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More than 20 million Americans have chronic kidney disease (CKD).[1] Compared with individuals with normal kidney function, those with CKD have greater odds of experiencing a premature cardiovascular event or death, independent of age, sex, and comorbid conditions.[2] Lower income and racial/ethnic minority patients are more likely to have kidney failure, placing a unique burden on health care systems that disproportionately provide for their care.[3] Although randomized controlled trials have shown that controlling blood pressure (BP) and reducing proteinuria with angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs) can delay CKD decline and progression to end-stage renal disease (ESRD) and decrease CKD-associated morbidity and mortality,[4-7] many individuals with CKD are not receiving these evidence-based treatments.[8] The failure to implement these best practices may be related to providers' poor CKD awareness[9,10] and limited confidence among primary care providers (PCPs) in delivering CKD care[11] in the context of inefficient health care systems that rely on overburdened providers to deliver chronic disease care to complex patients.

Disease registries are information platforms that can enhance chronic disease management.[12] Often embedded within electronic health records, disease registries capture and track patient-level data, allowing health care teams to proactively manage patients through "in-reach" at point of care or using "outreach" through patient contact outside of scheduled appointment times. Registries have been documented to improve the quality of chronic disease care,[13] including for patients with diabetes[14] and congestive heart failure.[15] Prior studies of CKD registries in the United States with computer-assisted prompts/alerts have not improved process outcomes related to CKD management or clinical outcomes,[16,17] though they have been successful in the United Kingdom.[18]

We hypothesized that the prior negative results in the United States were not likely due to unique refractoriness of CKD to the registry approach, but more likely because prior US CKD registries have focused on behavior change

among individual physicians rather than on entire health care teams and systems of care. With input from primary care leaders and quality improvement champions in a safety-net health system, we created an electronic CKD registry that identifies patients with CKD and provides data about CKD management to the entire health care team.[19] We then tested this approach to improve kidney health in a pragmatic trial in safety-net primary care clinics with a high burden of hypertension and CKD.

Methods

Study Population, Setting, and Study Design

This pragmatic trial (ClinicalTrials.gov study number NCT03473509) took place in 2 primary care clinics in San Francisco's public health care delivery system in 2013 to 2015. These clinics were selected because of the high prevalence of CKD among their patient populations and because one was an academic training clinic and the other was a community clinic without trainees. No other clinics were approached for participation. All PCPs who worked in practice teams and provided longitudinal primary care to patients were eligible to participate in this study. PCPs who solely provided specialty care, for example, human immunodeficiency virus (HIV) services or urgent care, were excluded. Practice teams that consisted of several physicians (with or without trainees), one nurse, nurse practitioners, medical assistants, and behaviorists were randomly assigned 1:1 to one of 2 arms with a random number generator: access to an electronic CKD registry or a usual-care registry for 12 months. This randomization scheme minimized contamination by medical assistants, who work with several providers within a given practice team, but led to differences in the number of PCPs randomly assigned to each arm due to different practice team sizes.

Approval to conduct this study was granted by the Human Research Protection Program and Institutional Review Board at the University of California, San Francisco, with waived patient consent. Medical directors of the 2 participating clinics provided verbal consent to participate in this study; health care providers in the clinics implied consent if they used the CKD registry. Health care teams randomly assigned to intervention had the option to not use the information provided by the CKD registry to manage their patients. The trial was not blinded to participating teams and providers, though the analytic team was blinded to group assignment.

Intervention

The CKD registry was designed to alert practice teams of a patient's CKD-relevant information and enhance guideline-concordant care delivery for patients with CKD. The CKD registry defined patients as having CKD if they had 2 values for dipstick albuminuria > 1+ or albuminuria with albumin excretion > 30 mg/g or 2 values of race-concordant estimated glomerular filtration rate (eGFR) of 15 to 59 mL/min/1.37 m^2 calculated using the Modification of Diet in Renal Disease (MDRD) Study equation (standard of care in the health system), separated by at least 3 months. It excluded individuals with eGFRs < 15 mL/min/1.37 m^2 and patients with ESRD. The CKD registry provided primary care practice teams with point-of-care data about patient-specific CKD status (eGFR and CKD on problem list), recent ambulatory clinic BP readings, status of ACE inhibitor/ARB prescription, and quantification of albuminuria (complete vs not complete). The CKD registry also provided data about diabetes care, immunization status, and data pertinent to age-appropriate cancer screening, to align with usual care. Medical assistants were encouraged to use these data to identify patients with CKD who needed albuminuria quantification and all patients (including those with CKD) who were due for cancer screening or immunizations. Point-of-care decision support embedded within the CKD registry reminded PCPs about guideline-concordant care for individuals with non–dialysis-requiring CKD: target BP < 140/90 mm Hg, prescription of ACE inhibitors/ARBs, avoidance of nonsteroidal anti-inflammatory medications, and prescription of statin medications (Fig S1). Quarterly feedback to practice teams and individual PCPs identified patients with CKD with BPs > 140/90 mm Hg, those not prescribed an ACE inhibitor/ARB, and those with persistent severely increased albuminuria for panel management to reach patients who did not regularly visit their PCP and would thus not benefit from the in-reach component of the CKD registry. A document with clinical guidance accompanied each quarterly report (Item S1). No additional resources were provided to the teams randomly assigned to the intervention arm of this study.

Usual care consisted of an electronic registry that was in use before trial implementation. It provided practice teams with point-of-care data about diabetes care, age-appropriate cancer screening, and immunizations, but no CKD-related data. Medical assistants were encouraged to use the usual-care registry to identify patients who were due for cancer screening or immunizations. Quarterly feedback was not provided for practice teams randomly assigned to receive usual care.

Outcomes

All outcome data were captured from the electronic health record. The primary outcome was change in ambulatory clinic systolic BP from baseline to 12 months. Medical assistants use standard oscillometric devices to check BP in all ambulatory clinics (including primary and specialty care) with a standardized protocol. If the first BP is elevated, a second BP is obtained. Although both BP measures are included in the medical record, only the second BP at each ambulatory clinic visit was used in this analysis. Secondary outcomes included changes in the proportion of patients with BP control defined as BP < 140/<90 mm Hg, proportion of patients whose albuminuria was quantified among those who had not